INDEX.

UNITED STATES OF AMERICA.

IN THE DISTRICT COURT OF THE UNITED STATES, MIDDLE DISTRICT OF GEORGIA—COLUMBUS DIVISION.

Criminal No. 3688.

JORDAN JAMES SULLIVAN, an individual, trading as SULLIVAN'S PHARMACY,

Appellant,

versus

UNITED STATES OF AMERICA,

Appellee.

Appearances:

Mr. J. Madden Hatcher and Mr. Robert M. Arnold, Columbus, Georgia, Attorneys for Appellant.

Mr. John P. Cowart, United States Attorney, and Mr. Jack J. Gautier, Assistant United States Attorney, Macon, Georgia, Attorneys for Appellee.

APPEAL from the District Court of the United States for the Middle District of Georgia, Columbus Division, to the United States Circuit Court of Appeals for the Fifth Circuit, returnable at the City of New Orleans, Louisiana.

3 F. D. C. No. 16600.

In the District Court of the United States within and for the Middle District of Georgia, Columbus Division.

United States of America,

vs.

Jordan James Sullivan, an individual, trading as Sullivan's Pharmacy.

Information No. 3688.

September Term, 1945.

John P. Cowart, Attorney for the United States, in and for the Middle District of Georgia, who for the said United States in this behalf prosecutes, in his own proper person comes into Court on this 26th day of December, A. D., nineteen hundred and forty-five, and with leave of the Court first had and obtained, gives the Court here to understand and be informed, as follows, towit:

That the Abbott Laboratories, trading and doing business at North Chicago, State of Illinois, did, within the period from on or about November 25, 1943 to on or about March 15, 1944, ship in interstate commerce from North Chicago, State of Illinois, to Atlanta, State of Georgia, consigned to the Abbott Laboratories, a number of boxes, containing a number of bottles, each bottle containing a number of tablets of a drug within the meaning of the Act of Congress of June 25, 1938, known as the Federal Food, Drug and Cosmetic Act (52 Statutes at Large, 1040; 21 U. S. C. 321(g)(2));

That one of said bottles containing said drug, when shipped in interstate commerce, as aforesaid, was labeled,

marked and branded by means of a label affixed thereto bearing the following printed and graphic matter, to-wit:

1000 Tablets (Bisected)
Sulfathiazole
(2-sulfanilamidothiazole)
0.5 Gm. (7.7 grs.)
Abbott
List No. 3430

Caution—To be used only by or on the prescription of a physician.

Warning: In some individuals Sulfathiazole may cause severe tox eactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request.

F5 Serial No. 311T237.

Abbott Laboratories,
North Chicago, Ill., U. S. A.

That thereafter, to-wit, on or about September 29, 1944, the said Abbott Laboratories at Atlanta, Georgia, did sell and deliver said bottle of said drug in the identical condition as when shipped in interstate commerce, as aforesaid, and labeled, marked and branded, as aforesaid to Jordan James Sullivan, an individual, operating under the name Lynwood Pharmacy, Columbus, Georgia, and the said Jordan James Sullivan transferred said bottle of

drug and caused said bottle of drug to be transferred to Sullivan's Pharmacy, Columbus, Georgia, a pharmacy owned and operated by said Jordan James Sullivan.

That on or about December 13, 1944, while a number of said tablets of said drug contained in said labeled bottle, as aforesaid, were being held for sale after shipment in interstate commerce, as aforesaid, at said Sullivan's Pharmacy the said Jordan James Sullivan did, at Columbus, Georgia, within the Columbus Division of the Middle Judicial District of Georgia and within the jurisdiction of this Court, then and there cause to be removed a quantity of said tablets of drug, to-wit, 12 tablets of said drug from said bottle labeled as aforesaid and sold and delivered, as aforesaid, and being held for sale as aforesaid, and did cause to be repacked said 12 tablets of said drug so removed into a box and did cause to be sold and disposed of the said box containing the said 12 tablets to one Joe P. Durham, solely upon the surrender by the said Joe P. Durham of money in payment therefor;

That said box into which said 12 tablets were repacked was labeled, marked and branded with the following written and graphic matter, and no other, to-wit:

Sulfothizal

That said act of causing the removal, repacking and disposal, as aforesaid, resulted in said 12 tablets of drug being misbranded within the meaning of said Act of Congress (21 U. S. C. 352(f)(1)), in that the labeling of said drug in said box failed to bear adequate directions for use, towit, in that the said box containing said 12 tablets of drug, bore no labeling containing directions for use;

That said act of causing the removal, repacking and disposal, as aforesaid, resulted in said drug in said box aforesaid being further misbranded within the meaning of said Act of Congress (21 U. S. C. 352(f)(2)), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users, in that the said box containing said tablets of drug bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration;

That said act by said Jordan James Sullivan, the defendant herein, of causing the removal from said labeled bottle, repacking into said box labeled as aforesaid and disposing of said 12 tablets of said drug, as aforesaid, was an act done by said Jordan James Sullivan while said article of drug was being held for sale after shipment in interstate commerce, as aforesaid, which resulted in said 12 tablets of drug being misbranded, as aforesaid, in violation of said Act of Congress (21 U. S. C. 331(k));

All of which was and is contrary to the form of the statute in such case made and provided and against the peace and dignity of the United States of America.

Count II.

And the said Attorney for the United States, in manner and form as aforesaid, also gives the Court here to understand and be informed that the Abbott Laboratories, trading and doing business at North Chicago, State of Illinois, did, within the period from on or about November 25,

1943, to on or about March 15, 1944, ship in interstate commerce from North Chicago, State of Illinois, to Atlanta, State of Georgia, consigned to the Abbott Laboratories, a number of boxes, containing a number of bottles, each bottle containing a number of tablets of a drug within the meaning of the Act of Congress of June 25, 1938, known as the Federal Food, Drug and Cosmetic Act (52 Statutes at Large, 1040; 21 U. S. C. 321(g)(2));

That one of said bottles containing said drug, when shipped in interstate commerce, as aforesaid, was labeled, marked and branded by means of a label affixed thereto bearing the printed and graphic matter borne on the bottle label described in the first count of this information which description of said bottle label in said first count is, by reference, hereby incorporated in this count;

That thereafter, to-wit, on or about September 29, 1944, the said Abbott Laboratories at Atlanta, Georgia, did sell and deliver said bottle of said drug in the identical condition as when shipped in interstate commerce, as aforesaid, and labeled, marked and branded, as aforesaid to Jordan James Sullivan, an individual, operating under the name of Lynwood Pharmacy, Columbus, Georgia, and the said Jordan James Sullivan transferred said bottle of drug and caused said bottle of drug to be transferred to Sullivan's Pharmacy, Columbus, Georgia, a pharmacy owned and operated by said Jordan James Sullivan;

That on or about December 14, 1944, while a number of said tablets of said drug contained in said labeled bottle, as aforesaid, were being held for sale after shipment in interstate commerce, as aforesaid, at said Sullivan's Pharmacy the said Jordan James Sullivan did, at Columbus, Georgia, within the Columbus Division of the Middle Judicial District of Georgia and within the jurisdiction

of this Court, then and there remove a quantity of said tablets of drug, to-wit, 12 tablets of said drug from said bottle labeled as aforesaid, and sold and delivered, as aforesaid, and being held for sale as aforesaid, and did repack said 12 tablets of said drug so removed into a box and did cause to be sold and disposed of the said box containing the said 12 tablets to one Herbert McLeod, Jr., solely upon the surrender by said Herbert McLeod, Jr., of money in payment therefor;

That said box into which said 12 tablets were repacked was labeled, marked and branded with the following written and graphic matter, and no other, to-wit:

Sulfathiazole

That said act of removal, repacking and disposal, as aforesaid, resulted in said 12 tablets of drug being misbranded within the meaning of said Act of Congress (21 U. S. C. 352(f)(1)), in that the labeling of said drug in said box failed to bear adequate directions for use, to-wit, in that the said box containing said 12 tablets of drug, bore no labeling containing directions for use;

That said act of removal, repacking and disposal, as aforesaid, resulted in said drug in said box aforesaid being further misbranded within the meaning of said Act of Congress (21 U. S. C. 352(f)(2)), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and methods and duration of administration in such manner and form, as are necessary for the protection of users, in that the said box containing said tablets of drug bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and

against unsafe dosage and methods and duration of administration.

That said act by said Jordan James Sullivan, the defendant herein, of removing from said labeled bottle, repacking into said box and disposing of said 12 tablets of said drug, as aforesaid, was an act done by said Jordan James Sullivan while said article of drug was being held for sale after shipment in interstate commerce, as aforesaid, which resulted in said 12 tablets of drug being misbranded, as aforesaid, in violation of said Act of Congress (21 U. S. C. 331(k));

All of which was and is contrary to the form of the Statute in such case made and provided and against the peace and dignity of the United States of America.

JOHN P. COWART,
United States Attorney for the
Middle District of Georgia.

Georgia,
Bibb County.

Comes now John P. Cowart, United States Attorney, who on oath deposes and says that the facts and things alleged in the foregoing criminal information are true and correct, to the best of his knowledge and belief.

JOHN P. COWART.

Sworn to and subscribed before me, this the 31 day of Dec., 1945.

WALTER F. DOYLE,
Deputy Clerk.

ORDER.

The foregoing information read and considered. Let the same be filed.

Further Ordered that copy of this criminal information be served upon the defendant named therein, and that the said defendant be and appear in the United States District Court for the Middle District of Georgia, Columbus Division, Columbus, Georgia, at 9:00 o'clock A. M., on the first Monday in March, 1946, to answer the charges contained therein.

This the 31st day of Dec., 1945.

T. HOYT DAVIS,
United States Judge.

Back or Cover of Information with Plea and Judgment.

PLEA.

Filed January 2nd, 1946.

* * * * * * * *

I, Jordan James Sullivan, having been advised of my Constitutional rights, and having had the charges herein stated to me, plead not guilty in Open Court, this 2 day of Sept., 1946.

J. MADDEN HATCHER,
Attorney for Jordan James Sullivan.

11 MOTION TO DISMISS.

(Title Omitted.)

Now comes Jordan James Sullivan, the Defendant in the above stated case, and before pleading to the merits of the above information, filed against him by the United States Attorney, moves the Court to dismiss and quash the information for the following reasons:

1. The allegations of said information are insufficient as a matter of law to constitute any offense against any of the laws of the United States of America.

2. It affirmatively appears from the allegations of said information that the alleged acts of this Defendant were not in interstate commerce, and were beyond the legislative power of Congress to regulate or control or punish.

3. Properly construed, Sections 331 (k), 352 (f) (1) and 352 (f) (2) of Title 21 U. S. C. only apply to misbranding in interstate commerce.

4. If Section 331 (k) of Title 21 U. S. C. is construed as applying to the alleged acts of this Defendant, then said section is unconstitutional, null and void, and in violation of the Tenth Amendment to the Constitution of the United States of America, which provides, "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the People", in that said section is beyond the legislative power of the Congress and is an invasion of the reserved police powers of the several States.

Wherefore, this Defendant prays that this motion be sustained and said information against him be dismissed and quashed and that he be discharged.

J. MADDEN HATCHER,
Attorney for Jordan James Sullivan, Defendant.

Filed February 8, 1946.

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OPINION.

(Title Omitted.)

DAVIS, District Judge:

This is a criminal prosecution by information in two counts,[1] charging violations of the Federal Food, Drug, and

[1] Count I (charging part):

"That the Abbott Laboratories, trading and doing business at North Chicago, State of Illinois, did, within the period from on or about November 25, 1943 to on or about March 15, 1944, ship in interstate commerce from North Chicago, State of Illinois, to Atlanta, State of Georgia, consigned to the Abbott Laboratories, a number of boxes, containing a number of bottles, each bottle containing a number of tablets of a drug within the meaning of the Act of Congress of June 25, 1938, known as the Federal Food, Drug and Cosmetic Act (52 Statutes at Large, 1040; 21 U. S. C. 321(g)(2));

"That one of said bottles containing said drug when shipped in interstate commerce, as aforesaid, was labeled, marked and branded by means of a label affixed thereto bearing the following printed and graphic matter, to-wit:

1000 Tablets (Bisected)
Sulfathiazole
(2-sulfanilamidothiazole) 0.5 gm. (7.7 grs.)
Abbott—List No. 3430

"Caution—To be used only by or on the prescription of a physician.

Warning: In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended. Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request.

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Abbott Laboratories.
North Chicago, Ill., U. S. A.

"That thereafter, to-wit, on or about September 29, 1944, the said Abbott Laboratories at Atlanta, Georgia, did sell and deliver said bottle of said drug in the identical condition as when shipped in interstate commerce, as aforesaid, and labeled, marked and branded, as aforesaid to Jordan James Sullivan, an individual, operating under the name Lynwood Pharmacy, Columbus, Georgia, and the said Jordan James Sullivan transferred said bottle of drug and caused said bottle of drug to be transferred to Sullivan's Pharmacy, Columbus, Georgia, a pharmacy owned and operated by said Jordan James Sullivan;

"That on or about December 13, 1944, while a number of said tablets of said drug contained in said labeled bottle, as aforesaid, were being held for sale after shipment in interstate commerce, as aforesaid, at said Sullivan's Pharmacy the said Jordan James

Cosmetic Act (21 U. S. C. 301 et seq.). It is alleged in each count, in substance, that a drug manufacturer in North Chicago, Illinois, shipped in interstate commerce to its distributor in Atlanta, Georgia, a bottle containing 1000 Sulfathiazole tablets; that the distributor thereafter sold and delivered said bottle of tablets to the defendant, the owner of drug stores in Columbus, Georgia; that while

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Sullivan did, at Columbus, Georgia, within the Columbus Division of the Middle Judicial District of Georgia and within the jurisdiction of this Court, then and there cause to be removed a quantity of said tablets of drug, to-wit, 12 tablets of said drug from said bottle labeled as aforesaid and sold and delivered, as aforesaid, and being held for sale as aforesaid, and did cause to be repacked said 12 tablets of said drug so removed into a box and did cause to be sold and disposed of the said box containing the said 12 tablets to one Joe P. Durham, solely upon the surrender by the said Joe P. Durham of money in payment therefor;

"That said box into which said 12 tablets were repacked was labeled, marked and branded with the following written and graphic matter, and no other, to-wit:

Sulfothizal

"That said act of causing the removal, repacking and disposal, as aforesaid, resulted in said 12 tablets of drug being misbranded within the meaning of said Act of Congress (21 U. S. C. 352(f)(1), in that the labeling of said drug in said box failed to bear adequate directions for use, to-wit, in that the said box containing said 12 tablets of drug, bore no labeling containing directions for use;

"That said act of causing the removal, repacking and disposal, as aforesaid, resulted in said drug in said box aforesaid being further misbranded within the meaning of said Act of Congress (21 U. S. C. 352(f)(2)), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users, in that the said box containing said tablets of drug bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration;

"That said act by said Jordan James Sullivan, the defendant herein, of causing the removal from said labeled bottle, repacking into said box labeled as aforesaid and disposing of said 12 tablets of said drug, as aforesaid, was an act done by said Jordan James Sullivan while said article of drug was being held for sale after shipment in interstate commerce, as aforesaid, which resulted in said 12 tablets of drug being misbranded, as aforesaid, in violation of said Act of Congress (21 U. S. C. 331 (k))."

Count II similar to Count I, except as to name of purchaser and relating to "Sulfathiazole" rather than "Sulfothiazal".

the tablets in said bottle were being held for sale at one of the defendant's drug stores, after shipment in interstate commerce, the defendant caused 12 tablets to be removed from the bottle and placed into a box and disposed of by sale; that the box into which the tablets were placed and which was sold bore only the label "Sulfothiazal", as described in Count One and "Sulfathiazole", as described in Count Two; that the act of removing, repacking, and disposal resulted in the drug being misbranded in two different respects under the Federal Food, Drug and Cosmetic Act.

It is charged that these acts constitute violations of Section 301(k) of the Act, (21 U. S. C. 331 (k)). The pertinent provision of this section of the Act is as follows:

"Section 301 (21 U. S. C. 331): "The following acts and the causing thereof are hereby prohibited: * * * (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a, * * * drug * * *, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

The defendant filed a Motion to Dismiss setting forth four grounds: (1) the allegations of the information are insufficient as a matter of law to constitute any offense against the laws of the United States; (2) the alleged acts of the defendant were not in interstate commerce and were beyond the power of Congress to regulate, control, or punish; (3) the applicable provisions of the law only apply to misbranding in interstate commerce; (4) that if section 301(k) of the Act is construed as applying to the alleged acts of the defendant, said section is unconstitutional as

being beyond the legislative power of Congress and an invasion of the reserved police powers of the states.

We will consider in this opinion

(1) Whether Section 301(k) of the Act is a lawful exercise by Congress of its powers under the commerce clause of the Constitution; and

(2) Whether the acts of the defendant alleged in the information are cognizable under this section of the Act.

(1)

The Federal Food, Drug and Cosmetic Act (passed in 1938) and its predecessor, the Food and Drug Act of 1906, have been held to be lawful exercises by Congress of its power under the commerce clause of the Constitution. In *Hipolite Egg Co. v. United States*, 220 U. S. 45 (1911), in speaking of the 1906 Act, the Court said at p. 57:

"The statute rests, of course, upon the power of Congress to regulate interstate commerce, and, defining that power, we have said that no trade can be carried on between the States to which it does not extend, and have further said that it is complete in itself, subject to no limitations except those found in the Constitution."

In *United States v. Dotterweich*, 320 U. S. 277 (1943), a case under the 1938 Act, the Court said at p. 280:

"The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience."

It is well settled that congressional authority under the commerce clause includes the power to regulate intrastate activities which "affect" interstate commerce or which are in the "flow" of interstate commerce. It was said in *Oklahoma v. Atkinson*, 312 U. S. 508, 526 (1941):

"As repeatedly recognized by this Court from M'Culloch v. Maryland, 4 Wheat. 316, to United States v. Darby, 312 U. S. 100, the exercise of the granted power of Congress to regulate Interstate Commerce may be aided by appropriate and needful control of activities and agencies which, though intrastate, affect that commerce."

In *National Labor Relations Board v. Jones & Laughlin Steel Corp.*, 301 U. S. 1, 36-37 (1937), the Court declared:

"The congressional authority to protect interstate commerce from burdens and obstructions is not limited to transactions which can be deemed to be an essential part of a 'flow' of interstate or foreign commerce. Burdens and obstructions may be due to injurious action springing from other sources. The fundamental principle is that the power to regulate commerce is the power to enact all appropriate legislation 'for its protection or advancement' * * *; to adopt measures 'to promote its growth and insure its safety' * * *; 'to foster, protect, control and restrain'. * * * That power is plenary and may be exerted to protect interstate commerce 'no matter what the source of the dangers which threaten it.'"

The following recent cases have determined some phases of intrastate activities that are properly subject to federal control. *Currin v. Wallace*, 306 U. S. 1 (1939); *Mulford v. Smith*, 307 U. S. 38 (1939); *United States v. Rock Royal Co-operative Inc.*, 307 U. S. 533 (1939); *United States v. Darby*, 312 U. S. 100 (1941); *United States v. Wrightwood Dairy Co.*, 315 U. S. 110 (1942).

The authority of Congress over goods which have moved in interstate has operated to prevent numerous acts to those goods: e. g., the imposition of discriminatory taxes, *Sonneborn v. Cureton* 262 U. S. 506 (1923); the requirement of label removal, *McDermott v. Wisconsin*, 228 U. S. 115 (1913); the receiving etc. of stolen motor vehicles, *Brooks v. United States*, 267 U. S. 432 (1925); the placing of restrictions on an importer in selling an article in convenient containers, *Baldwin v. Seeling*, 294 U. S. 511 (1935).

That Congress in enacting Section 301(k) of the Act intended to exercise its broad powers under the commerce clause is clearly expressed in the legislative history of the Act. In H. R. Rep. No. 2139, 75th Cong., (3rd Sess., 1938), submitted by the Committee on Interstate and Foreign Commerce to accompany S. 5, the bill which was enacted as the present Act, it was stated in speaking of Section 301:

"In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment."

One of the purposes of the Federal Food, Drug and Cosmetic Act is to "prevent the misuse of the facilities of interstate commerce in conveying to and placing before the consumer misbranded and adulterated articles of medicine or food". *McDermott v. Wisconsin*, 228 U. S. 115, 133 (1913); *United States v. Two Bags .... Poppy Seeds*, 147 F. (2d) 123, 127 (C. C. A. 6th, 1945). This purpose could not have been accomplished if the provision now being considered had been omitted. Its absence would have made it relatively simple, in many instances, to render nugatory the misbranding provisions of the Act

by simply shipping in interstate commerce properly labeled articles and misbranding them after the transportation had ended. Anticipating resort to such stratagem, whether as part of a scheme or not, Congress sought to prevent it by the enactment of subsection (k) which would preserve the integrity of labeling of an article that had been shipped in interstate commerce until it reached the consumer. "Any rule, . . . which is intended * * * to prevent the flow of commerce from working harm to the people of the nation, is within the competence of Congress. *Mulford v. Smith, supra.*

That federal authority extends far enough to control the labels on goods being offered for sale to consumers after shipment in interstate commerce was decided in *McDermott v. Wisconsin, supra.* In that case a Wisconsin statute required that certain syrups bear labels prescribed in the statute and none other. McDermott, a retail merchant in Wisconsin, received from Chicago a box containing 12 cans of syrup, which he placed on the shelves of his establishment for retail sale. The label of the syrup, when received by McDermott, complied with the Federal Food and Drugs Act of 1906, but did not comply with the state law. In order to meet the state law requirements, the labels of the cans would have had to be removed and new ones substituted. In holding that the state could not require the removal of the label that met the requirements of the federal law, the Court said at p. 133 in speaking of the state law:

"* * * to permit such regulation as is embodied in this statute is to permit a State to discredit and burden legitimate Federal regulations of interstate commerce, to destroy rights arising out of the Federal statutes which have accrued both to the Government and the shipper and to impair the effect of a Federal law which has been enacted under the Constitutional power of Congress over the subject."

By section 301(k) Congress has sought, not only to protect and foster interstate commerce, but also to prevent the impairment of the effect of other provisions of the Act. This it may lawfully do. "It is the law that when Congress properly enters the field of its authorized activity, it may not only adopt means necessary, but, in a like manner, means convenient to the exercise of its power." *Board of Trade v. Milligan*, 16 F. Supp. 859, 861. (W. D. Mo. 1936); aff'd 90 F. (2d) 855; cert. den. 302 U. S. 710 (1937).

In the McDermott case, the article that had been shipped in interstate commerce was subject to federal authority to the extent of prohibiting a state from interfering with its label. Such interference by the state impinged upon one of the lawful means that Congress had selected for the protection of the consumer. By section 301(k) Congress seeks to prevent individuals from interfering with labeling of articles that have been shipped in interstate commerce. Since federal authority can require the preservation of labels on articles that have been shipped in interstate commerce, notwithstanding attempted state regulation, it is a corollary that federal authority may require individuals to preserve such labels and punish acts that result in such articles being misbranded.

In *A. L. A. Schechter Poultry Corp. v. United States*, 295 U. S. 495 (1935), cited and strongly relied on by the defendant, the Court drew the distinction between intrastate activities that directly affect interstate commerce and those that affect it indirectly. The Court pointed out (p. 546) that the precise line, in determining how far the federal government may go, "can be drawn only as individual cases arise". The facts in the *Schechter* case, in which attempted regulations of intrastate activities were held to be beyond federal power, are clearly distinguishable from those in the instant case. There a "Live Poultry Code", which had been promulgated under the Nation-

al Industrial Recovery Act, attempted to regulate almost every phase of the intrastate activities of the poultry business. These included hours, wages, labor conditions, number of employees, trade practices, etc. The regulations were general in nature and related to the conduct of the business, whether or not the commodity dealt with had been transported in interstate commerce. In holding that the regulations were invalid the Court recognized (p. 544) that it is the "effect upon interstate commerce" not "the source of the injury" which is the criterion of federal power. In the statute here assailed the very article on which the act was done which resulted in its misbranding must have moved in interstate commerce. To hold that Congress has no power to prohibit such wrongful acts would permit the use of the facilities of interstate commerce to place before the consumer misbranded goods. "The power to regulate interstate commerce includes the power to prohibit its use to facilitate wrongful and injurious acts and practices." *Bailey v. United States*, 74 F. (2d) 451 (C. C. A. 10, 1934).

An important Supreme Court pronouncement with respect to the Food and Drugs Act of 1906 appears in the dissenting opinion of Justice Holmes in *Hammer v. Dagenhart*, 247 U. S. 251 (1918). The majority opinion was recently expressly overruled by a unanimous Court in *United States v. Darby, supra*, where on page 115, the Court referred to "the powerful and now classic dissent of Mr. Justice Holmes". In his dissent in the *Dagenhart* case, Justice Holmes stated on page 279:

"The Pure Food and Drug Act which was sustained in Hipolite Egg Co. v. United States, 220 U. S. 45, with the intimation that 'no trade can be carried on between the States to which it (power of Congress to regulate commerce) does not extend', 57, applies not merely to articles that the changing opinions of the time condemn as in-

trinsically harmful but to others innocent in themselves, simply on the ground that the order for them was induced by a preliminary fraud. *Weeks v. United States*, 245 U. S. 618. It does not matter whether the supposed evil precedes or follows the transportation. It is enough that in the opinion of Congress the transportation encourages the evil."

Here Justice Holmes gave recognition to the proposition that in the Food and Drugs Act of 1906 Congress did not confine its regulation of interstate commerce in such merchandise to the period of transportation alone, but properly struck at evils intimately associated with such commerce, though they might arise prior or subsequent to the transportation.

By the statute here in question Congress has in effect declared that if the facilities of interstate commerce are used for the shipment of goods, no person may thereafter, while the goods are being held for sale, do any act with respect to the goods which misbrands them. The mischief, which the statute seeks to prevent, has a direct effect on interstate commerce. To hold that Congress may not prevent such acts would permit the facilities of interstate commerce to be used to the detriment of the public.

So far as the Court is aware, there are only two reported cases that deal with the interpretation of this provision of the law. One of these cases is *United States v. Lee*, 131 F. (2d) 464 (C. C. A. 7, 1942), an injunction proceeding under section 302 of the Act (21 U. S. C. 332) to restrain, among other things, violations of section 301(k). The defendant there caused circulars to be printed in which false claims were made for his drug products and after the goods were shipped in interstate commerce the drugs and circulars were displayed together which resulted in the goods being misbranded. The Circuit Court, in holding that this was a violation of section 301(k) which could be restrained, said (p. 466):

"It (the Federal Food, Drug and Cosmetic Act) was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the Act if it occurs while the articles are being held for sale."

The other case which deals with this provision of the law is *United States v. 7 Jugs .... Dr. Salsbury's Rakos*, 53 F. Supp. 746 (D. Minn., 1944), a seizure under the Act. The Court there commented as follows (p. 756):

"This Court does not in this proceeding propose to mark out the limits of Section 301(k). Seemingly, however, it was enacted by Congress under its authority to regulate activities affecting interstate commerce. See *National Labor Relations Board v. Jones & Laughlin Steel Corp.*, 301 U. S. 1. In referring to alteration, mutilation, destruction, obliteration, or removal of labels, this section at least suggests the possibility that what it contemplates is a lawful use by a drug of the facilities of interstate commerce followed by some activity which causes it to be misbranded."

By the Federal Food, Drug and Cosmetic Act, Congress has sought to prevent the use of facilities of interstate commerce in conveying to and placing before consumers adulterated and misbranded articles. That it may lawfully do this, the Court believes, is no longer open to question. Keeping within Constitutional limitation of authority Congress may determine for itself the means necessary to make its purpose effective. By section 301(k) Congress had exhibited the character of the means it deemed necessary to carry out its purpose, and the Court thinks it has kept within Constitutional bounds.

(2)

The plan of section 301 of the Act clearly demonstrates the purpose of Congress. Subsection (a) prohibits the introduction into interstate commerce of an article that is misbranded at the time introduction takes place; sub-section (b) prohibits the misbranding of an article in interstate commerce; sub-section (k) prohibits the doing of any act with respect to an article after shipment in interstate commerce and while held for sale, that results in the article being misbranded.

It is unnecessary in considering this case to determine whether or not the article on which the alleged acts were done were in interstate commerce at the time the misbranding took place. It might well be that in the instant case the article while on the shelf of the retailer was in interstate commerce. If this were so, the acts done might be acts of misbranding in interstate commerce, and a violation of Section 301(b). The situation set forth in subsection (k) "while such article is held for sale after shipment in interstate commerce", does not preclude the possibility that the article at the same time may be in interstate commerce. But, under section 301(k) it is sufficient to show interstate shipment of the article and the doing of the prohibited act while the article was held for sale. It is apparent that Congress intended to preserve the integrity of the labeling of an article that had been shipped in interstate commerce until it reached the consumer, even though the article was no longer in interstate commerce.

The information charges that the act of the defendant, in causing the removal, repacking, and disposal of the tablets, resulted in the drug being misbranded within the meaning of 21 U. S. C. 352(f)(1) and (2). These provisions are as follows:

"A drug or device shall be deemed to be misbranded—
(f) Unless its labeling bears (1) adequate directions for

use and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement."

It will be observed from the allegations of the information that the bottle containing the tablets, which was shipped in interstate commerce, did not bear adequate directions for use but bore the so-called "prescription legend". The regulation promulgated under the proviso of 21 U. S. C. 352(f) exempted this article from bearing adequate directions for use. This regulation in effect at the time of the alleged violation,[2] 21 C. F. R. Cum. Sup. Sec. 2.106(b) provided, among other things that a shipment of a drug shall be exempt from bearing adequate directions for use if it is made for use exclusively by or on prescriptions of physicians and bears the "prescription legend". The exemption is to remain effective until the drug is dispensed upon and under labels bearing the directions for use specified in prescriptions of physicians. This regulation as it affects the present case would require the drug to be sold on a physician's prescription and to bear the directions for use specified in the prescription. The "prescription legend" is not a substitute for adequate directions for use.

The bottle containing the tablets of drug when shipped in interstate commerce, traveling under the exemption, was labeled to comply with the law. It is charged that the act of the defendant in causing the removal, repacking

[2] A new regulation with somewhat modified provisions concerning exemptions under this section became effective on October 10, 1945.

and disposal of the tablets of drug in a container bearing only the written matter "Sulfothiazal" or "Sulfathiazole" resulted in its misbranding.

It was strongly contended here by the defendant that the acts which are alleged to constitute the violation were not one of those particularly enumerated in the statute, viz: "Alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling." This argument is untenable for two reasons. First, such acts are in fact alteration or obliteration of part of the label, and second, such acts, if not one of those enumerated, is the doing of some other act, other than those enumerated, with respect to the drug.

The bottle label which was proper bore considerable printed matter, including the name of the drug "Sulfathiazole" and the "prescription-legend", and required warnings. Clearly, if part of the label had been obliterated, leaving only "Sulfathiazal", misbranding would have resulted. Likewise, if the article is repacked into a container which bears only the printed matter "Sulfathiazal", there is equally a violation as being a combination of obliteration and alteration of the label.

Apart from this, the language of the statute "or the doing of any other act with respect to a * * * drug", includes any other act other than those enumerated in the opening clause of sub-section (k). No restriction is made as to the character of the act prohibited, except that it must be "with respect to" the drug. Had it been the intention of Congress to prohibit acts upon the article itself, or to the original container, it would have been sufficient to proscribe any other act to the article. Instead, however, the more inclusive term "with respect to" was used. Not only are acts done to the article itself prohibited, but all acts falling within the larger category are prohibited by the statutory language. In *United States v. Lee, supra,* the Court held that displaying circulars which

contained false and misleading statements together with drugs that had been shipped in interstate commerce and resulted in the drugs being misbranded was cognizable under this section of the act.

The design of Congress "to extend the protection of consumers contemplated by the law to the full extent constitutionally possible" is clearly expressed in the legislative history. Congress in section 301(k) did not use any language that would indicate that "held for sale after shipment in interstate commerce" referred to the original consignee, or while the article was in original unbroken packages, unloaded, or unsold. Congress used the broad language "while * * * held for sale." In order to give effect to the purposes of the Act, the protection of the consumer, the prohibitions relating to the article must go along with it while it is being held for sale by anybody, whether the original interstate consignee, wholesaler, distributor, or retailer. The article in the hands of any dealer and until it reaches the ultimate consumer is being held for sale. This thought as it applied to producers was expressed by the Court in *Hipolite Egg Co. v. United States, supra*, where it was said:

"All articles, compound or single, not intended for consumption by the producer, are designed for sale, and, because they are, it is the concern of the law to have them pure."

Obviously, the defendant in this case, a retail druggist, who is charged with doing the prohibited acts, from the time he received the article until it was disposed of was holding it for sale. The buying of drugs and holding them for sale was part of his business. The language of the statute coupled with the statement from the legislative history, read in the light of the purposes of the Act, affords, in this Court's opinion, no room for doubt

that the acts charged are within the meaning and purpose of the statute.

The defendant in this case, as retail druggists generally do, obtained his supply from a distributor within the state. If section 301(k) is limited to a situation where the drugs which are being held for retail sale were received directly from outside the state, the protection of the public will be extensively curtailed. If retailers find that they can evade federal jurisdiction by purchasing drugs through local wholesalers, after receipt by the latter in the channels of interstate commerce, this provision of the act is nullified and the statute rendered partly ineffective. A statute should not be construed as to render it partly ineffective or inefficient or to cause public injury or inconvenience, if it can be construed in a way that will make it effective. *United States v. Powers*, 307 U. S. 214 (1939); *Bird v. United States*, 187 U. S. 118 (1902); *Sunshine Anthracite Coal Co. v. Adkins*, 310 U. S. 381 (1940).

The Supreme Court in *United States v. Antikamnia Chemical Co.*, 231 U. S. 654, 667 (1914) said of the Food and Drugs Act of 1906:

"The purpose of the law is the ever insistent consideration in its interpretation."

And in *United States v. Dotterweich, supra*, the Court said of the present Act:

"The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation, if it is to be treated as a working instrument of government and not merely as a collection of English words."

In construing section 301(k) the Court should be guided by the purposes of the Act, the intention of Congress therein evidenced, and seek to make that intention effectual. *United States v. Standard Downer Co.*, 274 U. S. 225 (1927); *Rogers v. Peck*, 199 U. S. 425 (1905). The Court should look to the policy of the legislation as a whole, the reason for its enactment and its antecedent history and give it an effect in accordance with its design and purpose, so that its purpose may not fail. *Ozawa v. United States*, 260 U. S. 178 (1922); *United States v. American Trucking Ass'ns*, 310 U. S. 534 (1940). Regard should also be had to the evils which called forth the statute (*Fasulo v. United States*, 272 U. S. 620 (1926)), and a construction should be adopted which serves to correct the evil and defeat the wrong it was its purpose to frustrate. *Bernier v. Bernier*, 147 U. S. 242 (1893); *Rhodes v. Iowa*. 170 U. S. 412 (1898).

The Federal Food, Drug and Cosmetic Act is a remedial statute, intended to protect the public health and pocket book, and should be liberally construed. *United States v. Dotterweich, supra; United States v. Two Bags .... Poppy Seeds, supra, United States v. 7 Jugs .... Dr. Salsbury's Rakos, supra; United States v. Research Laboratories*, 126 F. (2d) 42 (C. C. A. 9, 1945); *United States v. Commercial Creamery Co.*, 43 F. Supp. 714, (E. D. Wash., 1942).

So construing section 301(k) of the Act there can be no doubt that the acts of the defendant alleged in the information constitute violations of those provisions of the law.

The defendant's motion to dismiss will be Denied.

Ordered filed, this the 19 day of June, 1946.

T. HOYT DAVIS,
United States District Judge.

Filed June 20, 1946.

33 ORDER DENYING MOTION TO DISMISS.

The defendant's motion to dismiss the criminal information filed in the above stated case was orally argued before the Court by counsel for both sides, and written briefs were filed. The Court has carefully considered the questions involved and its conclusions are set forth in an opinion filed this date.

Whereupon, it is Ordered and Adjudged by the Court that the motion to dismiss be and the same is hereby Denied.

This the 19th day of June, 1946.

T. HOYT DAVIS,
United States District Judge.

Filed June 20, 1946.

Mr. Cowart:

Your Honor please, we are calling for trial before the Court without a jury the case of United States versus Jordan James Sullivan, trading as Sullivan's Pharmacy, Information No. 3688.

The Court:

Why not try it to a jury?

Mr. Cowart:

Mr. Hatcher specifically waives trial by jury and we request the Court to try it without a jury. As a matter of fact, it will be tried on stipulation.

The Court:

Well, if you have stipulated the facts. This is in that matter where I passed on the motion to dismiss.

Mr. Hatcher:
Yes, sir.

Mr. Cowart:
Mr. Hatcher has stipulated that he would stipulate that—

Mr. Hatcher:
Let me make that statement.

Mr. Cowart:
All right, make it for the record.

Mr. Hatcher:
Your Honor please, we are willing to stipulate—

The Court:
You mean you do stipulate?

Mr. Hatcher:
Yes, sir—that the defendant, Jordan James Sullivan, on or about December 13, 1944, caused to be sold 12 sulfothiazal tablets, to Joe P. Durham, in a box, which was labeled only "Sulfothiazal"; that immediately prior to the sale, the 12 tablets were removed from a bottle which had originally contained 1000 of such tablets, which was then on the shelf of defendant's drugstore in Columbus, Georgia; that said bottle of 1000 tablets was labeled in the manner set forth in the information; that said bottle had previously been purchased on or about September 29, 1944 by the defendant, from Abbott Laboratories in Atlanta, and had been shipped on or about that date from Atlanta, Georgia to Columbus, Georgia; that said bottle, along with a number of other like bottles, had previously between November 25, 1943 and March 15, 1944, been shipped in interstate commerce by Abbott Laboratories in Chicago, from Chicago, Illinois, to Atlanta, Georgia.

Mr. Cowart:

North Chicago, I believe that was.

Mr. Hatcher:

—North Chicago, Illinois, to Atlanta, Georgia. That is our stipulation, if the Court please.

Mr. Cowart:

Now, will you stipulate further that they were being held by this druggist on his shelves for sale, after such shipment? That is what the information states.

Mr. Hatcher:

I am willing to stipulate they were on his shelves and that he ran a retail drug-store in Columbus, Georgia, and that the 12 tablets were sold over the counter in said retail store in Columbus, Georgia.

Mr. Cowart:

That is all right. Now, that is in Count One. There is a second count there as to the purchase by another agent. It is exactly the same situation but a different purchase. I have the agents here and am in position to prove it; that is, just on the sale.

Mr. Hatcher:

I am willing to stipulate as to that count, as I stated. I had rather not stipulate as to this count. I am willing to stipulate as to the shipment.

Mr. Cowart:

All of it except the actual sale?

Mr. Hatcher:

Yes.

The Court:
What about the label on the second count?

Mr. Hatcher:
No, sir.

Mr. Cowart:
You stipulate only as to the interstate shipment of the bottle?

Mr. Hatcher:
Yes.

Mr. Cowart:
Then, I want to swear, if Your Honor please, Mr. Herbert McLeod, Jr. ..., Mr. Hatcher, there is one other thing in connection with that first count: Will you stipulate further that the man to whom the drug was sold did not have a prescription, Durham?

Mr. Hatcher:
No, sir, I am not willing to stipulate as to that.

Mr. Cowart:
I want Mr. Durham and Mr. McLeod to both hold up their right-hands.

(Two witnesses sworn.)

Mr. Cowart:
Do you have any witnesses?

Mr. Hatcher:
No.

Mr. Cowart:
Do you want our witnesses excluded?

Mr. Hatcher:
No.

37 MR. JOE P. DURHAM, witness sworn in behalf of the Government, testified on

Direct Examination.

By Mr. Cowart:

Q. Mr. Durham, are you a Food and Drug Inspector?

A. Yes, sir.

Q. Did you have occasion to come to Columbus on or about December 13, 1944, and visit Sullivan's Pharmacy, operated by Jordan James Sullivan here in Columbus?

A. Yes, sir.

Q. On that occasion did you make a purchase of 12 tablets of sulfothiazal drug from Mr. Sullivan?

A. No, sir, I made the purchase of sulfothiazal from Mr. Meadows, one of the pharmacists in Mr. Sullivan's drugstore.

Q. Do you have the drugs that you purchased?

A. Do I have them?

Q. Do you have the box that they were sold to you in?

A. No, sir, I have not.

Q. What was the labeling on the box that the tablets were in?

A. Sulfothiazal.

Q. Was there any other description on the box, other than that?

A. No, sir.

Q. Did you have a prescription?

A. No, sir.

Mr. Arnold:

Your Honor please, we move to exclude the evidence of the witness as to what was written on the box which

he claims the tablets were sold in, on the ground that the box itself would be the highest and best evidence.

Mr. Cowart:
He stipulated that, if Your Honor please.

The Court:
I understood that it was agreed that he sold it.

Mr. Arnold:
That was in the other count.

Mr. Hatcher:
Durham is in the first count? I thought it was McLeod. He says he bought them from another person.

Mr. Cowart:
From another druggist, that's right.

Mr. Hatcher:
I was understanding the first count was a sale made by Mr. Sullivan.

Mr. Cowart:
No, it was made by one of his druggists in the drug-store to this Joe P. Durham. Now, the second count may be the one where it was sold by Mr. Sullivan.

Mr. Hatcher:
Well, that is the one that I had reference to.

Mr. Cowart:
That is the one you were stipulating on?

Mr. Hatcher:
That's right.

Mr. Cowart:

We can stipulate what you stated as to the second count instead of the first count?

Mr. Hatcher:

That's right.

(Mr. Cowart):

Q. Mr. Durham, did you have a doctor's prescription calling for this drug?

Mr. Arnold:

Just a minute. As I understand it, we are now talking about the box that was sold by the pharmacist, is that correct?

Mr. Cowart:

No, we are talking about the box that was sold by the pharmacist to this Drug Inspector, not the original bottle, because there is a stipulation about the bottle containing the 1000 tablets.

Mr. Hatcher:

That's right.

Mr. Arnold:

No, I am talking about the box that this gentleman purchased, this particular box that he purchased. He purchased this from the pharmacist, did he not?

Mr. Cowart:

That's right.

Mr. Arnold:

Now, that is what I wish to object to, what was written on there because we have not stipulated anything as to that particular box.

Mr. Cowart:
That's correct.

Mr. Arnold:
We move to exclude that because he said he got the box and it is not here.

The Court:
Well, if he can account for it, I will permit him to do that.

(Mr. Cowart):
Q. Mr. Durham, did you get the tablets in a box or package, or how did they come?
A. In a box.
Q. What kind of box?
A. In a small white box, what we usually call a "pill box", about two inches by maybe half an inch.
Q. What did you do with the box?
A. I identified that with what we call sample number 64091-F, and put the date that I purchased it, 12-13-44, and my initials "J. P. D." on there. I officially wrapped that box with paper and put an official United States Government, Food and Drug, seal on that; and on that seal I again put the number, 64091-F, 12-13-44, Joe P. Durham; and delivered it to the Chief Chemist of the Food and Drug laboratory in Atlanta, Mr. A. M. Henry, on the 18th of December.
Q. And so far as you know, that is where it is now?
A. Yes, sir.
Q. Now, what was the labeling on that box, Mr. Durham?
A. I copied the labeling off on my collection report, written in pencil, the information I took off of the box, was the word "Sulfothiazal".
Q. How was that spelled?
A. Sulfathiozole, unless I am mistaken in it.

Q. Now Mr. Durham, was there any other direction or any other directions on the box other than the word "Sulfathiozole"?

A. Nothing else on the box.

Q. Until you put something else on there and that was your entries?

A. Until I put the sample number and my initials on it.

Q. How many tablets were contained in that box?

A. Twelve.

Q. Did you turn the tablets, along with the box, over to the chemist?

A. Yes, sir.

Q. Did you have a prescription from a doctor?

A. No, sir.

Q. Did you buy this medicine from the druggist without a prescription of any sort?

A. I did.

Q. Tell the Court just how you come about buying it. What did you say to him and what did he say to you?

A. Well, when I went in the store there was an elderly gentleman at the back that was sweeping the floor and I walked on back toward the back, and he asked me what he could do for me. I told him, "I would like to have about an ounce of Tincture of Mercresin, and a dozen sulfathiazole tablets." He went back into what we call the "prescription room", or another little room in the back part of the building; and came back in a minute or two and said he did not have the Tincture of Mercresin. I asked him if there was another drugstore in that vicinity. It was the first time I had been in that drugstore and the first time in that section of Columbus. And he said "No, there was not." He went back into the prescription room and in about a minute came back with this small box and handed it to me, and made the statement that that would clear up my throat. I had appar-

ently a little cold when I went in there but I didn't tell him what I wanted with the tablets or anything. I asked for a dozen sulfathiazole tablets. I do not know what he assumed. I asked him how much the tablets were and he said a dollar, I mean 75 cents. I gave him a dollar bill and he gave me back a quarter. I took the product and left the store and stopped under the light on the outside and wrote the sample number, the date and my initials on it.

Q. Did you ever any time tell him what you were going to use it for?

A. No, I did not.

Q. And you had no doctor's prescription for it?

A. I had no doctor's prescription.

Mr. Cowart:
He's with you.

Mr. Hatcher:
No questions.

42 MR. HERBERT McLEOD, JR., witness sworn in behalf of the Government, testified on

Direct Examination.

By Mr. Cowart:
Q. What is your name?

Mr. Hatcher:
Now, is that in reference to what we have stipulated?

Mr. Cowart:
This is the second count.

Mr. Hatcher:

We have stipulated as to that, except the prescription. We did not stipulate on that.

(Mr. Cowart):

Q. Mr. McLeod, did you on or about the 14th day of December go to the drugstore operated by Mr. Sullivan, known as Sullivan's Pharmacy, here in Columbus?

A. I did.

Q. At that time did you make any purchase of 12 sulfathiazole tablets?

A. I did.

Q. Did you at that time surrender to him a doctor's prescription, giving directions as to the use and number of tablets to be bought?

A. No, sir.

Q. Did you state to him what was your purpose in buying them, what you were going to use them for?

A. I did not.

Q. You bought them without any directions from a physician?

A. That's right.

Q. And without his knowledge of what you were going to use them for?

A. I am sure he did not have any way of knowing what I was going to use them for.

Q. Did Mr. Sullivan sell you those particular tablets? Just for the purpose of clearing this record here, did Mr. Sullivan sell you those tablets?

A. Yes, sir.

Q. The defendant on trial here?

A. Yes, sir.

Q. Did Mr. Sullivan know whether or not you were a Food and Drug Inspector at the time?

A. I am sure he did not because I had never seen him before.

Q. You did not tell him you were a Food and Drug Inspector?

A. No, sir.

Cross Examination.

By Mr. Madden Hatcher:

Q. This is Mr. McLeod?

A. Yes, sir.

Q. To refresh your recollection, Mr. McLeod, didn't you tell Mr. Sullivan that you were very familiar and knew all about sulfathiazole?

A. No, sir.

Q. You did not?

A. No, sir.

Q. You did not tell him that you wanted it for a cold?

A. No, sir.

Q. Mr. McLeod, did Mr. Sullivan, after making that sale to you and after you made known your official capacity, did he refuse to furnish on your request the name and address of the person from whom he purchased or received such articles?

A. He did. I asked for his invoice covering.

Q. And he gave it to you, didn't he?

A. No, sir, he said he kept his invoices at home.

Q. Well, didn't he go with you to his house?

A. What?

Q. Didn't he go with you to his home?

A. No, sir.

Q. He didn't go with you to his home?

A. I have never been to his home.

Q. He didn't tell you who he bought it from?

A. The bottle was labeled "Abbott", and he told me he didn't know where he bought it; that some time ago, about a year and a half ago, he bought a large quantity of tablets from a lot of different people, because he thought there was going to be a shortage.

Q. Well, did he refuse to furnish you on your request with the name of the person from whom he bought it?

A. Yes, sir.

Q. What did he say to you, please sir? What did you ask him and what did he say?

A. I said I would like to see the invoice covering this bottle. He said, "I don't have it." He said "I keep my invoices at home", and that was at night and he was apparently the only pharmacist there, and he didn't want to leave the store; and he said he would be there the next day. I went around there the next day but he never did go get the invoice.

Q. You didn't go and Mr. Durden didn't go out there?

A. Mr. who?

Q. Mr. Durham, I mean?

A. To his house?

Q. Yes.

A. I don't know whether Mr. Durham went to his house or not.

Q. Well, you all were working together in Columbus at the time?

A. Yes, sir.

Mr. Arnold:

Judge, would you permit me to ask him this?

Cross Examination.

By Mr. Arnold:

Q. You asked him where his invoices were?

A. Yes, sir.

Q. And he told you they were at home?

A. Yes, sir.

Q. He didn't refuse to tell you where he had gotten these articles, did he?

A. Well, not in an outright refusal, in that sense of the word, but he didn't have them.

Q. Well, he didn't refuse to tell you? He said he didn't know because he had the invoices at home, that is correct?

A. That's right.

Q. So, your statement then that he refused to tell you was a conclusion on your part, wasn't it?

A. I do not know that I stated that he refused.

Q. You do now state though that he did not refuse but simply stated his invoices were at home?

A. Yes, sir.

Q. And he could not furnish it to you at that time?

A. That's right.

Q. However, you looked on the bottle, didn't you?

A. Yes, sir.

Q. And you got the label on the bottle and that showed the manufacturer, didn't it?

A. Yes, sir.

Q. Who was the manufacturer?

A. Abbott Laboratories, North Chicago. In fact, I took the bottle.

Q. He did not then refuse to give you the name and address of the person from whom he purchased it, that is Mr. Sullivan, did he?

A. He didn't give it to me.

Q. He didn't refuse, did he?

A. Well, I asked him for it and I didn't get it.

Q. His explanation was, he had them at home?

A. Yes, sir.

Q. Did you ask him for any documents pertaining to the delivery of the sulfathiazole tablets that he himself bought? Did you ask him for any document?

A. The documents I asked for were the invoices and the freight records covering that shipment.

Q. What?

A. I asked to see the records covering that shipment. By records I meant the invoice from the distributor and the freight bill from the common carrier.

Q. That is all you asked for?

A. Yes, sir.

Q. What did he say about the common carrier records?

A. He didn't have it there. I do not remember whether he said he had one or not.

Q. So, the substance of it is, he said he would go out to his house with you next day and get them, didn't he?

A. Yes, sir.

Q. You didn't go with him, did you?

A. I do not remember going. I can look it up in my notebook. He said he would but I sure don't remember doing it. . . . No, I did not go out there with Mr. Sullivan.

Q. Now, you and Mr. Durham were working together, weren't you?

A. On some jobs, yes.

Q. On this job you were working together? You were sent down here to work the town together, weren't you?

A. I wouldn't say working together.

Q. Well, why were you here at the same time?

A. We are Food and Drug Inspectors and we have business down here in Columbus quite frequently.

Q. Did you come down together?

A. I believe we did.

Q. How did you come?

A. In a car.

Q. In a car?

A. Yes.

Q. Well, you were working the town together and you knew he was here for that purpose, didn't you?

A. For what purpose?

Q. For the purpose of investigating these druggists on sulfathiazole?

A. Yes, sir, I knew that.

Q. So, you were working together for the Food and Drug people, weren't you?

A. We were working for the Food and Drug Administration.

Q. Did you go back to Atlanta together?

A. Yes, sir.

Q. Did you compare notes on what you had done?

A. That's right.

Q. Did you stay at the hotel together?

A. Yes, sir.

Q. Have the same room?

A. Had what they call a suite. I had to sleep on a day-bed and they had the bed.

Q. Did you discuss with him what he had done and discuss with him what you had done?

A. Yes, sir, but we didn't actually go into any places together until after it was all over.

Q. Well, I know that.

A. Well, I thought that's what you meant by working together.

Q. Now, after you had gone around and purchased them, then you went back together, didn't you?

A. That's right.

Q. And asked for these documents, explained to them that you were Food and Drug Inspectors? Then, you went back and asked Mr. Sullivan for these documents that you are telling me about?

A. I asked him the same night that I bought the tablets.

Q. But you went back the next day?

A. Yes, I went back the next day.

Q. You were with Mr. Durham then, weren't you?

A. That I don't know.

Q. Did you go any place together?

A. Yes, sir.

Q. It was your practice to go together, wasn't it?

A. No.

Q. After it was all over, I mean, and you went back to ask for the documents or to tell them who you were?

A. I wouldn't say it was a practice.
Q. Well, you did it, didn't you?
A. Did what?
Q. If you will listen very carefully, I think you can get my question.

The Witness:
Your Honor, am I on trial here or Mr. Sullivan?

The Court:
No, sir.

Mr. Cowart:
I do not see the relevancy of this line of questioning.

The Court:
I thought there was a stipulation.

Mr. Arnold:
There was a stipulation but I am getting this to bring out the other part. I want to ask Mr. Durham.

Mr. Cowart:
I think you are confused on the men that went to his house.

Mr. Arnold:
Well, I was trying to show that they went together and that the act of one was really the act of the other.

The Court:
Well, that wouldn't follow.

Mr. Arnold:
I mean by that the act of the Administration.

51 MR. JOE P. DURHAM, witness sworn in behalf of the Government, being recalled by Defendant, testified further on

Cross Examination.

By Mr. Arnold:

Q. Mr. Durham, did you go to the house with Mr. Sullivan, his house?

A. Yes, sir.

Q. To get the documents?

A. Yes, sir.

Q. Did he give them to you?

A. I got what records he had.

Q. He did not refuse to give them to the Food and Drug Administration?

A. I will make this statement: That was about two weeks after Mr. McLeod was in Columbus. Mr. McLeod was on leave without pay over in Alabama and didn't know anything about it.

Q. What I am getting at though is that the documents that you asked for and all he had, he gave you, didn't he?

A. I may make this statement: I do not say that the documents that I asked for were given me, no. I don't know. There were documents given me in a box, in several boxes. They were scattered all over Mr. Sullivan's house in boxes, with newspapers, magazines and first one thing and another. You could not make head nor tail of any of them.

Q. But he gave you what he had?

A. He gave me that stuff.

Q. He gave you what he had?

A. He gave me that stuff and I went through it.

Q. What did you do with it?

A. I looked at it.

Q. Did you take any of it with you?

A. No, sir.

Q. Then, you were out there with him?

A. Yes, sir, he carried it down to the drugstore for me to go through, and then it was turned back over to him.

Q. Did those documents contain invoices?

A. They had a few invoices, had invoices, bills and letters, and just a general conglomeration of material.

Mr. Hatcher:

That is all.

Mr. Cowart:

That is all you have.

The Court:

I believe the venue was stipulated here in Columbus?

Mr. Cowart:

Yes, sir, it is here in Columbus.

Mr. Hatcher:

Yes, sir, it is here in Columbus, these cases.

Mr. Arnold:

If Your Honor please, there are just two points that I want to speak briefly about.

ARGUMENT.

The Court:

I spent a good deal of time on this matter. It was an intriguing question to me. I reached a definite conclusion that these acts charged here did constitute an offense under that Act, and that the Act was valid in that respect.

The Court:

Now the stipulation here and the evidence, in my opinion, if my theory of it is correct, does show this man

is guilty, if my theory of the Act and construction of it is correct. If I am wrong on it, why then he has not committed any offense, but that is my view about it; and, of course, I would hold him guilty under the stipulations and under the evidence here. Now, do you want to conclude the record now?

Mr. Hatcher:
Yes, sir.

The Court:
What did I give those others? I think I fined those others $250 and put them on probation.

Mr. Cowart:
They varied, if Your Honor please, from $200 to $500 and $750 was the highest.

Mr. Hatcher:
If the Court please, may I just make a motion for the record for an acquittal, for a judgment of acquittal, if that is necessary, just to preserve the point that the evidence is insufficient.

The Court:
Yes, and I overrule that motion and find the defendant guilty. . . . This man is still in the drug business?

Mr. Hatcher:
Yes, sir, and let me make this statement: This man has in effect been under probation ever since December 13, 1944 and I ask you to take that into consideration.

The Court:
Well, I will give him what I gave the others, as I remember, in his class. I will suspend the imposition of sentence

and put him on probation. I will let him pay a fine of $200 and serve two years on probation.

Mr. Roberts, Chief Probation Officer:
Is that a condition of probation?

The Court:
Upon the payment of a fine of $200. Now, about the supervision, I do not know that it is necessary for the Probation Officer to supervise him because the Food and Drug people will be inspecting him from time to time.

Mr. Arnold:
We would like to further complete the record by filing a notice of appeal and, if Your Honor would agree to it, we would like for you to let him pay the fine into the Court in lieu of bond, to be held subject to final disposition.

The Court:
In lieu of a bond?

Mr. Arnold:
Yes.

The Court:
Well, he could just put up the fine.

Mr. Cowart:
I think he has got to pay the fine prior to appealing or else make bond for it.

The Court:
If you pay the fine, I think that might interrupt your appeal.

Mr. Arnold:

We do not want to pay the fine.

The Court:

If he wants to put up $200 cash bond in lieu of another bond, not as payment of the fine, but as a bond, he can post a cash bond of $200 and that will stay the fine. When you file your notice of appeal and give your bond, the execution of the sentence is suspended until the matter is finally determined. I would really be glad for you fellows to test it out because it affects druggists all over the country. If I am right about it, it ought to be established and if I am wrong about it, it ought to be established.

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55 JUDGMENT

The dft., Jordan James Sullivan, having pled not guilty and having waived a trial by jury and the same being tried by the Court by agreement of the U. S. and the dft. and after hearing the evidence, I find the defendant guilty, this the 2nd day of Sept., 1946.

T. HOYT DAVIS,
U. S. Judge.

District Court of the United States, Middle District of Georgia, Columbus Division.

United States of America,
vs.
Jordan James Sullivan, an individual, trading as Sullivan's Pharmacy.

Indictment No. .....

Information No. 3688.

Crime: Vio. Federal Food, Drug & Cosmetic Act.

The defendant having been convicted and it having been made to appear to the satisfaction of the Court that the ends of justice and the best interests of the public, as well as the defendant, will be subserved by suspending the imposition of sentence and by placing the defendant upon probation under the provisions of the Probation Act, approved March 4, 1925, it is

Considered and Adjudged that the imposition of sentence be and the same is hereby suspended, and that defendant be and is hereby placed upon probation under the provisions of said Act and upon the followin terms and conditions:

1. Defendant shall pay to the United States at this time $200.00 as a condition of probation.

2. The probation period shall be for Two (2) years.

3. Defendant shall report as directed by the Probation Officer, Charles E. Roberts, Macon, Georgia.

4. During the maximum period for which defendant might now be sentenced, or during the period of probation, whichever is greater, the conduct and behavior of defendant shall be good in all respects, and he shall refrain from violation of any and all State and Federal penal laws, and from any activity, conduct, or behavior tending toward any such violation.

5. Service of said sentence shall be without supervision.

In open Court, this 2nd day of September, 1946.

T. HOYT DAVIS,
United States Judge.

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57 NOTICE OF APPEAL.

Filed Sept. 3, 1946.

In the District Court of the United States within and for the Middle District of Georgia, Columbus Division.

United States of America,
vs.
Jordan James Sullivan, an individual, trading as Sullivan's Pharmacy.

Information No. 3688.

September Term, 1945.

1. Name and address of appellant: Jordan James Sullivan, 1411 Wynnton Road, Columbus, Georgia.

2. Name and address of appellant's attorney: Robert M. Arnold, Columbus, Georgia; and J. Madden Hatcher, Columbus, Georgia.

3. Offense: Misbranding in violation of Section 331 (k) of Title 21 of the United States Code.

4. Concise statement of judgment and sentence: Judgment of conviction, dated September 2, 1946, imposing a fine of Two Hundred Dollars ($200.00) upon appellant and placing appellant upon probation for a term of two (2) years.

5. Name of institution where now confined, if not on bail: Appellant not confined.

The above-named appellant hereby appeals to the United States Circuit Court of Appeals for the Fifth Cicruit from the above-stated judgment.

Dated: September 3, 1946.

ROBERT M. ARNOLD,
J. MADDEN HATCHER,
Attorneys for Appellant.

Filed September 3, 1946.

STATEMENT OF POINTS ON WHICH APPELLANT INTENDS TO RELY ON THE APPEAL.

58 (Title Omitted.)

Comes now Jordan James Sullivan, the appellant, by and through his attorneys, Robert M. Arnold and J. Mad-

den Hatcher, and hereby states that he intends to rely on the appeal on the following points:

1. The allegations of said information are insufficient as a matter of law to constitute any offense against any of the laws of the United States of America and particularly Section 331 (k) of Title 21 of the United States Code.

2. The evidence was insufficient as a matter of law to sustain the conviction of the appellant of any offense against any of the laws of the United States of America and partciularly Section 331 (k) of Title 21 of the United States Code.

3. The two (2) over-the-counter retail sales, each of twelve (12) Sulfathiazole tablets, made by the appellant at his retail drugstore in Columbus, Georgia, were in intrastate commerce and did not and could not have any direct or substantial effect on interstate commerce.

4. Congress has no power under the commerce clause of the Constitution to regulate the intrastate over-the-counter retail sale of a drug which has come to rest within the state after shipment in interstate commerce unless such sale directly and substantially affects interstate commerce.

5. Properly construed, Sections 331 (k), 352 (f) (1) and 352 (f) (2) of Title 21 of the United States Code only apply to misbranding in interstate commerce.

6. Under Section 333 (c) (1) of Title 21 of the United States Code, it was necessary for the Government to allege and prove that the appellant acted in bad faith or refused to furnish on request the name and address of the

person from whom he purchased or received the drug in interstate commerce and copies of all documents, if any there were, pertaining to the delivery of the drug to him.

7. The evidence affirmatively shows that appellant acted in good faith in selling and delivering said Sulfathiazole tablets and that he did not refuse to furnish on request of an officer or employee duly designated by the administrator, the name and address of the person from whom he purchased or received such drug and copies of all documents that he had pertaining to the delivery of said drug to him.

8. Section 331 (k) of Title 21 of the United States Code and particularly the language "or the doing of any other act with respect to a drug . . . if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded" is too vague, indefinite and uncertain to be enforcible as a criminal statute and to sustain a conviction of appellant for having made the two (2) retail sales as described in the information for the reason that such language does not adequately inform appellant that such sales will make him subject to the criminal penalties of the act.

9. If Section 331 (k) of Title 21 of the United States Code is construed as applying to the alleged acts of this appellant, then said section is unconstitutional, null and void, and in violation of the Tenth Amendment to the Constitution of the United States of America, which provides, "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people", in that said section is beyond the legislative power of the Congress and is an invasion of the reserved police powers of the several States.

This 18 day of September, 1946.

(S.) ROBERT M. ARNOLD,

(S.) J. MADDEN HATCHER,

Attorneys for Appellant, Jordan James Sullivan.

Filed September 18, 1946.

DESIGNATION OF CONTENTS OF RECORD ON APPEAL.

60 (Title Omitted.)

Comes now the appellant, Jordan James Sullivan, by and through his attorneys, Robert M. Arnold and J. Madden Hatcher, and hereby designates the following portions of the record, proceedings and evidence to be contained in the record on appeal:

1. The Information No. 3688, dated December 31, 1945.

2. The appellant's Motion to Dismiss said Information, the Order of the District Court, dated June 19, 1946, denying appellant's Motion to Dismiss and the Opinion of the Court, of the same date.

3. The Reporter's Transcript of the Stipulations, Proceedings and Evidence at the trial of appellant.

4. The Judgment and Sentence of the Court, dated September 2, 1946.

5. Appellant's Notice of Appeal, dated September 3, 1946.

6. This Designation by appellant of the Contents of the Record on Appeal.

7. Appellant's Statement of the Points on which he intends to Rely on the Appeal.

This 18th day of September, 1946.

(S.) ROBERT M. ARNOLD,
(S.) J. MADDEN HATCHER,
Attorneys for the Appellant,
Jordan James Sullivan.

Filed September 18, 1946.

61 CLERK'S CERTIFICATE.

In the District Court of the United States, Middle District of Georgia—Columbus Division.

Jordan James Sullivan, an individual, trading as Sullivan's Pharmacy, Appellant,
vs. Criminal No. 3688.
United States of America, Appellee.

United States of America,
Middle District of Georgia.

I, GEORGE F. WHITE, Clerk of the District Court of the United States in and for the Middle District of Georgia, do hereby certify that the foregoing and attached 61 pages contain a true, full, complete and correct copy of the original record and all proceedings had in the above stated cause, as specified in the designation of contents of record on appeal of counsel herein and as the same remains of record and on file in the Clerk's Office of the said District Court at Columbus, Georgia.

In Witness Whereof, I have hereunto set my hand and the official seal of the said District Court at Macon, Georgia, this 27th day of September, 1946.

GEORGE F. WHITE,
(Seal) Clerk, United States District Court, Middle District of Georgia,
By WALTER F. DOYLE,
(Walter F. Doyle),
Deput Clerk.

That thereafter the following proceedings were had in said cause in the United States Circuit Court of Appeals for the Fifth Circuit, viz:

Argument and submission

Extract from the Minutes of April 21st, 1947

No. 11774

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY

v.

UNITED STATES OF AMERICA

On this day this cause was called, and, after argument by R. M. Arnold, Esq., and J. Madden Hatcher, Esq., for appellant, and Vincent A. Kleinfeld, Esq., Attorney, Department of Justice, for appellee, was submitted to the Court.

Opinion of the court filed

May 12, 1947

In the United States Circuit Court of Appeals for the Fifth Circuit

No. 11774

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY, APPELLANT

v.

UNITED STATES OF AMERICA, APPELLEE

Appeal from the District Court of the United States for Middle District of Georgia

(May 12, 1947)

Before SIBLEY, MCCORD, and LEE, Circuit Judges

SIBLEY, Circuit Judge: Sullivan, a local retail merchant in Columbus, Georgia, was convicted under the Federal Food, Drug, and Cosmetics Act, 52 Stats. 1040, Sect. 301, (c) and (k), 21 U. S. C. A. § 331 (c) and (k), for selling to two federal inspectors two

lots of twelve tablets each of sulfathiazole taken from a bottle on the shelves of his drug store which had contained 1,000 tablets. The facts as alleged in the information and stipulated or proven on the trial are these: Between Nov. 25, 1943, and March 15, 1944, Abbott Laboratories, doing business in North Chicago, Illinois, shipped in interstate commerce to Abbott Laboratories, at Atlanta, Georgia, a number of boxes containing bottles of drugs, one of them being this bottle of 1,000 tablets of sulfathiazole, which was duly labeled as such, with a caution that they are to be used only by or on the prescription of a physician, and with the name and Chicago address of Abbott Laboratories. This bottle so labeled was on Sept. 29, 1944, in Atlanta sold to Sullivan, and by him transferred in intrastate commerce to his pharmacy in Columbus, and placed on his shelves for retail sales to customers. On Dec. 13, 1944, the two lots of twelve tablets each were taken from the bottle, placed in pasteboard pill boxes, with only the word sulfathiazole (slightly misspelled) on them, and sold to the federal inspectors. The label on the bottle was not defaced or changed, and the bottle was seen and afterwards taken in charge by the inspectors. A motion to dismiss the information as not charging a federal crime, and one for a judgment of acquittal because none was proved, were overruled and this appeal taken.

The general constitutionality of the federal Act under the commerce clause of the Constitution is admitted. The contentions are that the Act is not intended to operate on retail sales over the counter after interstate commerce has ended, by one who was not the importer; that the language is not clear enough to make criminals of such sellers; and that if construed to apply to them the Act is to that extent beyond the power of Congress.

It will be noted that the only interstate commerce here involved is the transportation of bottles of drugs in boxes from Chicago to Atlanta at least nine months before the sales here in question. The boxes came to rest in Atlanta and were opened by the importer, Abbott Laboratories, and the bottles were put in their stock of drugs in Atlanta for sale. Over six months thereafter Sullivan bought one bottle, which is conceded to have been duly labeled, and put it into his stock of drugs at Columbus for retail sales, where the bottle stayed for three more months. If the criminal provisions relied on apply here, they apply to all intrastate sales of imported drugs after any number of intermediate sales within the State and after any lapse of time; and not only to such sales of drugs, but also to similar retail sales of foods, devices and cosmetics, for all these are equally covered by these provisions of the Act. We are not able to conclude that the Act is to be so construed

as to bring within these penal provisions most of the sales in all drug stores, beauty parlors, barber shops and retail grocery stores in the United States.

The general purpose of the Act is declared in its simple title: "An Act to prohibit the movement in interstate commerce of adulterated and misbranded foods, drugs, devices and cosmetics, and for other purposes." Section 301 (c) prohibits (under penalty by Section 303), "The receipt in interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and the proffered delivery thereof for pay or otherwise." Sullivan clearly did not receive in interstate commerce any misbranded drug, nor did he proffer delivery of any in interstate commerce. A moderately strict construction of this penal provision would confine it to shippers and to importers in interstate commerce, and proffers of sale by the latter. Sullivan was a party to intrastate sales only. Moreover since this bottle was at all times duly labeled and not misbranded, no one violated this provision by receiving or proffering delivery of it.

Section 301 (k) prohibits "The alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug device or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded." The labeling here was not removed or mutilated; but an act was done with respect to the drug, towit, the removal of some of it from the labeled bottle and the placing of it in a box not sufficiently labeled under the Act, after shipment in interstate commerce and while the drug was held for sale, so that this portion of the drug became misbranded. Therefore in their broadest possible sense these words may include what happened. But we are of opinion that they ought not to be taken so broadly, but held to apply only to the holding for the first sale by the importer after interstate shipment. Since importation by merchants of all merchandise is for the very purpose of sale, the importation, as has always been held, remains incomplete till its purpose is thus realized. Brown vs. Maryland, 12 Wheat. 419. The words of Section (k), "held for sale after shipment in interstate commerce," naturally refer to this first sale by the merchant importer. It was this sale which was involved in McDermott vs. Wisconsin, 228 U. S. 115, and in Baldwin vs. Seelig, 294 U. S. 511, much relied on by the government. We do not doubt, however, that the United States can prohibit the destruction of the labeling under which interstate commerce occurred, by anyone at any time, in order to preserve the evidence of what was done during

the interstate movement, as is fairly held in the McDermott case cited; but here this evidence was never meddled with, but went unaltered into the hands of the inspectors, and it shows a correct labeling. These main provisions of subsection (k) were fully complied with. The attempt here made is to extend subsection (k) so as to make criminal all retail sales from the interstate package, though made clearly in intrastate commerce, unless the label on the interstate package which has been broken be reproduced on the retail package. We believe no grocer or druggist thus breaking an interstate package for a retail sale has understood this was necessary, and it is said this case is the first effort to apply the federal Act in this way. If the "holding for sale" is held to refer to all would-be sellers no matter where or when or in what quantities, of all foods and drugs and cosmetics which at some time had moved in interstate commerce, the field of enforcement of the Act will be multiplied many times. The reason urged for so expanding it, towit, the protection of ultimate consumers, only makes another difficulty; for while Congress may regulate interstate commerce to any extent and almost for any purpose it thinks proper, this extended application would be really a direct regulation for police purposes of what is plainly intrastate commerce, which is the peculiar province of the State.

And the State of Georgia has not neglected her duty. Title 42 of the Georgia Code deals with the subject of selling and labeling foods, drugs and toilet articles, with several cooperative references to the federal laws and regulations, as in Sect. 42–110, 42–111; and 42–802, 42–806. Sections 42–701 and ff. regulate the dispensing of poisons, this legislation dating back to the year 1876. Sections 42–101 and ff. embody comprehensive laws on the subject of foods and drugs passed in 1906 and 1908. The Uniform Narcotic Drugs Act of 1935 is found in Sections 42–801 and ff. The Dangerous Drug Act of 1939 is in Sections 42–708 and ff. The last expressly covers the derivatives and compounds of sulfanilamide, and the label on the bottle here in controversy indicates that sulfathiazole is such, so that this Georgia Act applies to these sales, and Sullivan appears to have violated it here. It would seem the federal inspectors should have reported them to the Georgia inspectors. It is probable that other States have similar laws, reducing the need for Congress to interfere thus in intrastate commerce, if it has the power.

In passing this Act Congress in its title indicated that its main and direct concern was with "the movement in interstate commerce." Until that movement is complete and the importer has sold his original packages the State cannot interfere. Congress

regulated what the Constitution directly authorizes. There is no indication of any intention to regulate intrastate commerce because of any burdensome effect on interstate commerce. The talismanic expression "Affecting interstate commerce" is not used, as in the National Labor Relations Act passed shortly before. In interpreting and applying those words in National Labor Relations Board vs. Jones and Laughlin Steel Corp., 301 U. S. 1, the court was careful to point out the rule of construction of statutes that a construction will not be adopted that is of doubtful consitutionality, in this very matter of federal intrusion upon the domain of the States, saying at page 30: "We have repeatedly held that as between two possible constructions of a statute by one of which it would be unconstitutional and the other valid, our plain duty is to adopt that which will save the Act. Even to avoid a serious doubt the rule is the same (citing numerous cases.)"[1] Also in Federal Trade Commission vs. Bunte Bros., 312 U. S. 349, we read: "The construction of Sect. 5 urged by the Commission would give the federal agency control over myriads of local businesses in matters heretofore traditionally left to custom or local law. * * * An inroad upon local conditions and local standards of such farreaching import as involved here ought to await a clearer mandate from Congress." Much more ought unambigous and clear words to be required when statutes creating criminal offenses are for construction. United States vs. Wiltberger, 5 Wheat. 76; United States vs. Harris, 177 U. S. 305; Kraus vs. United States, 327 U. S. 614.

The purpose of this Act being to regulate "movement in interstate commerce" of foods, drugs and cosmetics, and the general purpose of subsection (k) being to prohibit mutilation of the labeling on the packages which so moved, we do not find the proposed application of the ejusdem generis words "Any other act" plain enough to make criminals of retail grocers and druggists who did not import but who break and sell intrastate from the imported packages without mutilating the labeling.[2] We thus find it unnecessary to determine the constitutionality of the federal regulation of intrastate sales as here contended for, by denying that doubtful construction.

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[1] Sliechter Poultry Corporation vs. United States, 295 U. S. 495, though not exactly in point, is enough to raise serious doubt in this case.

[2] Armour and Co. vs. Dakoto, 240 U. S. 510, and Weigle vs. Curtice Bros. Co., 248 U. S. 285, held that retail sales from broken interstate packages were not governed by the Federal Food and Drugs Act then in force but by the State law, partly for constitutional reasons; but the present Act differs enough to make these decisions probably not controlling here. In United States vs. Dotterweich, 320 U. S. 277, the shipment of the repacked drugs was in interstate commerce and was prosecuted under Section 301 (a), and the construction of (k) was not involved at all.

The judgment is reversed with direction to acquit the defendant below.

Judgment reversed.

Judgment

Extract from the Minutes of May 12th, 1947

No. 11774

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY

v.

UNITED STATES OF AMERICA

This cause came on to be heard on the transcript of the record from the District Court of the United States for the Middle District of Georgia, and was argued by counsel;

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court in this cause be, and the same is hereby, reversed with direction to acquit the defendant below.

Clerk's Certificate

United States of America

United States Circuit Court of Appeals, Fifth Circuit

I, Oakley F. Dodd, Clerk of the United States Circuit Court of Appeals for the Fifth Circuit, do hereby certify that the pages numbered from 58 to 67 next preceding this certificate contain full, true and complete copies of all the pleadings, record entries and proceedings, including the opinion of the United States Circuit Court of Appeals for the Fifth Circuit, in a certain cause in said Court, numbered 11774, wherein Jordan James Sullivan, trading as Sullivan's Pharmacy, is appellant, and United States of America is appellee, as full, true and complete as the originals of the same now remain in my office.

I further certify that the pages of the printed record numbered from 1 to 57 are identical with the printed record upon which said cause was heard and decided in the said Circuit Court of Appeals.

In testimony whereof, I hereunto subscribe my name and affix the seal of the said United States Circuit Court of Appeals, at my office in the City of New Orleans, Louisiana, in the Fifth Circuit, this 3rd day of June A. D. 1947.

[SEAL]

(S) OAKLEY F. DODD,
Clerk of the United States Circuit Court of Appeals, Fifth Circuit.

U. S. GOVERNMENT PRINTING OFFICE, 1947

Supreme Court of the United States

No. 121, October Term, 1947

Order allowing certiorari

Filed October 13, 1947

The petition herein for a writ of certiorari to the United States Circuit Court of Appeals for the Fifth Circuit is granted. And it is further ordered that the duly certified copy of the transcript of the proceedings below which accompanied the petition shall be treated as though filed in response to such writ.

U. S. GOVERNMENT PRINTING OFFICE: 1947

No. 1473 121

In the Supreme Court of the United States

OCTOBER TERM, 1946

UNITED STATES OF AMERICA, PETITIONER

v.

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIFTH CIRCUIT

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In the Supreme Court of the United States

OCTOBER TERM, 1946

No. 1473

UNITED STATES OF AMERICA, PETITIONER

v.

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIFTH CIRCUIT

The Acting Solicitor General, on behalf of the United States, prays that a writ of certiorari issue to review the judgment of the Circuit Court of Appeals for the Fifth Circuit, reversing the judgment of the District Court for the Middle District of Georgia convicting respondent for violating Section 301 (k) of the Federal Food, Drug, and Cosmetic Act.

OPINIONS BELOW

The opinion of the circuit court of appeals (R. 58–63) is not yet reported. The opinion of the district court (R. 11–27) is reported at 67 F. Supp. 192.

JURISDICTION

The judgment of the circuit court of appeals was entered May 12, 1947 (R. 63). The jurisdiction of this Court is invoked under Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925. See also Rules 37 (b) (2) and 45 (a), Federal Rules of Criminal Procedure.

QUESTIONS PRESENTED

1. Section 301 (k) of the Federal Food, Drug, and Cosmetic Act prohibits the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to," a drug, if such an act is done while "such article is held for sale after shipment in interstate commerce and results in such article being misbranded." The question is whether this provision extends to a retail druggist who misbrands a drug after it has reached his shelves.

2. If so, whether Section 301 (k) is a constitutional exercise of the commerce power.

STATUTE AND REGULATION INVOLVED

The Federal Food, Drug, and Cosmetic Act, June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, *et seq.*), provides in pertinent part:

> SEC. 301. The following acts and the causing thereof are hereby prohibited:
>
> * * * * * *
>
> (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that

is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. [21 U. S. C. 331 (c).]

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded. [21 U. S. C. 331 (k).]

* * * * *

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine. [21 U. S. C. 333 (a).]

* * * * * *

SEC. 502. A drug or device shall be deemed to be misbranded—

* * * * * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or

against unsafe dosage or methods of duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement. [21 U. S. C. 352 (f).]

Regulation 2.106 (b) promulgated by the Acting Administrator on April 10, 1941, 6 Fed. Reg. 1920, provides:

(b) A shipment or other delivery of a drug or device shall be exempt from compliance with the requirements of clause (1) of section 502 (f) of the Act if:

(1) Such shipment or delivery is made for use exclusively by or on the prescription of physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device;

(2) Adequate directions for so using such drug or device are available in scientific publications or otherwise;

(3) The label of such drug or device bears the statement "Caution: To be used only by or on the prescription of a ------", or "Caution: To be used only by a ------", the blank to be filled in by the word "Physician", "Dentist", or "Veterinarian", or any combination of two or all of such words, as the case may be;

(4) No representation appears in the labeling of such drug or device with respect to the conditions for which it is to be used; and

(5) In the case of a drug which is not designated solely by a name recognized in an official compendium and which is fabricated from two or more ingredients, its label also bears the quantity or proportion of each active ingredient.

Such exemption shall remain valid until all of such shipment or delivery is used by physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device, or is dispensed upon, and under labels bearing the directions for use specified in, prescriptions of such physicians, dentists, or veterinarians. But if such shipment or delivery, or any part thereof, is otherwise disposed of as a drug or device, such exemption shall thereupon expire. The causing by any person of such an exemption so to expire shall be considered to be an act of misbranding for which such person shall be liable unless, prior to such disposition, such drug or device is relabeled to comply with clause (1) of section 502 (f) of the Act.

* * * * *

STATEMENT

On December 31, 1945, an information in two counts (R. 2–8) was filed in the United States District Court for the Middle District of Georgia

charging respondent with violations of the Federal Food, Drug, and Cosmetic Act. Each count alleged that a bottle containing sulfathiazole tablets was shipped in interstate commerce from North Chicago, Illinois, to Atlanta, Georgia; that the bottle was then sold to respondent with the same label as when shipped in interstate commerce; that on a specified occasion, while respondent held the drug for sale in his drug store, he removed 12 tablets from the bottle, repacked them in a box bearing on the label only the name of the drug, and sold them; that the drug, as so repacked and sold, did not bear adequate directions for use as required by Section 502 (f) (1) of the Act and did not bear certain warnings required by Section 502 (f) (2) of the Act; and that the drug was thus misbranded, in violation of Section 301 (k) of the Act.[1]

On February 8, 1946, respondent filed a motion to dismiss the information (R. 10), in which he urged that no offense was charged; that his acts were not in interstate commerce and were thus beyond the power of Congress to regulate; that properly construed, Sections 301 (k) and 502 (f) (1) and (2) apply only to misbranding in interstate commerce; and that if Section 301 (k) were construed to apply to respondent's acts, it is un-

[1] The first count charged the respondent with causing the doing of the prohibited act. The second count alleged that respondent performed the act.

constitutional and in violation of the Tenth Amendment. On June 19, 1946, the district court filed an opinion (R. 11–27) rejecting respondent's contentions.

Regulation 2.106 (b) of the Food and Drug Administration (*supra*, pp. 4–5) permits the shipment of various drugs in interstate commerce without appropriate instructions as to use if the drug is labeled with the prescription legend—"Caution: To be used only by or on the prescription of a physician"—and if various other specified conditions are satisfied. The regulation is designed to deal with those drugs for which adequate directions for lay use cannot be devised. As we show below, it was pursuant to this regulation that the drug in this case was shipped in interstate commerce.

Respondent waived a jury trial (R. 28). The undisputed evidence at the trial showed that during the period between November 25, 1943, and March 15, 1944, Abbott Laboratories shipped to itself at Atlanta, Georgia, bottles containing 1,000 tablets of sulfathiazole and bearing a warning that the tablets were to be "used only by or on the prescription of a physician." Respondent purchased one of these bottles in Atlanta, and it was shipped to him at Columbus, Georgia, where he operated a retail drug store. On December 13, 1944, an inspector of the Food and Drug Administration purchased, without a doctor's pre-

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scription, 12 sulfathiazole tablets from respondent's drug store. On the following day another inspector made a similar purchase. In both instances, immediately prior to the sale, the tablets which were sold were removed from the container in which they were shipped and which bore the warning against their use without a physician's prescription;[2] they were placed in small containers on which only the name of the drug—sulfathiazole—appeared (R. 29–31, 32–34, 35–37, 38).

Respondent was convicted on both counts (R. 49). The court suspended imposition of sentence

[2] The label on the bottle which was shipped in interstate commerce and from which the 12 tablets were removed in each instance read as follows (see R. 3, 29):

"1000 Tablets (Bisected)
"Sulfathiazole
"(2-sulfanilamidothiazole)
"0.5 Gm. (7.7 grs.)
"Abbott
"List No. 3430

"Caution—To be used only by or on the prescription of a physician.

"Warning: In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

"Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request.

"F5 Serial No. 311T237.

"Abbott Laboratories,
"North Chicago, Ill., U. S. A."

and placed respondent on probation for two years on condition that he pay a fine of $200 (R. 50–51). Upon appeal to the Circuit Court of Appeals for the Fifth Circuit, the judgment was reversed on the ground that respondent's acts did not constitute a violation of Section 301 (k) of the Federal Food, Drug, and Cosmetic Act (R. 58–63). It was the view of the court that Section 301 (k) applies only to the act of the importer of the interstate shipment and that it does not apply to a retailer who secures the drug intrastate from the importer.

SPECIFICATION OF ERRORS TO BE URGED

The circuit court of appeals erred:

1. In reversing the judgment of the district court.

2. In holding that the act of a retailer in removing a drug, which he held for sale after shipment in interstate commerce, from its properly labeled interstate container and placing it in another container without appropriate labeling is not a violation of Section 301 (k) of the Federal Food, Drug, and Cosmetic Act.

REASONS FOR GRANTING THE WRIT

This case presents for the first time in this Court the question of the proper construction to be given Section 301 (k) of the Federal Food, Drug, and Cosmetic Act. As we shall show, the construction adopted by the Fifth Circuit un-

necessarily limits the plain words of the provision to the extent of rendering it largely meaningless, and it seriously impairs the functioning of the Food and Drug Administration in its efforts to protect the consuming public against the ill effects of misbranding.

1. Section 301 (k) is a statutory embodiment of this Court's recognition in *McDermott* v. *Wisconsin*, 228 U. S. 115, that even after an article which has been shipped in interstate commerce reaches the retailer's shelves, the label under which it traveled in the stream of commerce must be protected. In the *McDermott* case, the reason for protecting the label was to make it possible to ascertain whether the article had lawfully been shipped in interstate commerce. Section 301 (k) is not limited to this purpose of protecting the label. As the House Committee Report (No. 2139, 75th Cong., 3d sess., p. 3) explains:

> In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph [301] (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment.

The words of the statute plainly reflect this purpose. For in broad terms they proscribe the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect

to" a drug if such an act is done while "such article is held for sale after shipment in interstate commerce and results in such article being misbranded." So far as constitutionally permissible, this provision prohibits the doing of anything to a label on a drug or to the drug itself which results in the drug being misbranded within the meaning of the Act.

If the drug in question had been shipped in interstate commerce with a label containing merely the word "sulfathiazole," it would have been misbranded. For such a label does not contain adequate directions for use and the necessary warnings, as required by Section 502 (f) (1) and (2) of the Act. Here, after the drug reached the retailer's shelf and while he was holding it for sale, he did an act which resulted in the drug being misbranded within the meaning of these provisions. While he did not tamper with the interstate label itself, he did, by removing part of the contents from the properly labeled container and placing them in an improperly labeled container, accomplish the same result of misbranding in such a way that the drug as relabeled could not lawfully have been shipped in interstate commerce. This was, we submit, the doing of "any other act with respect to" a drug which "results in such article being misbranded." The court below conceded that the words of Section 301 (k), "in their broadest possible sense," reach the act done here (R. 60).

The court held, however, that the portion of Section 301 (k) which proscribes acts of the character involved here must be limited to "the first sale by the importer after interstate shipment" (R. 60).[3] On this theory, if the retailer himself imports the goods from outside the state, as in the *McDermott* case, he would be subject to the Act. But if the interstate importer is a distributor who sells intrastate to a retailer, the former may not do anything with the article which results in misbranding, but the retailer may do so with impunity. There is nothing in the language of Section 301 (k), which extends to articles "held for sale after shipment in interstate commerce," which justifies such a distinction between retailers purchasing interstate goods from interstate or intrastate wholesalers. The consequence of the adoption of any such distinction would be to permit any retailer to circumvent the statute by purchasing from a wholesaler within the state instead of directly from the producer or from an extrastate wholesaler.

It is plain from the Fifth Circuit's opinion that the court gave Section 301 (k) a restrictive construction, notwithstanding the plain words of the

[3] The court apparently thought that any mutilation, alteration, destruction, obliteration, or removal of the whole or any part of the interstate label itself by any dealer in the state of destination, whether on the first or subsequent transfers within the state, was within the valid scope of Section 301 (k) (see R. 60–61).

statute and the evident Congressional purpose to the contrary, because it had doubts that the provision could constitutionally extend beyond the act of the importer to that of the ultimate retailer. We are unable to agree with the court below that the Constitution requires this result. If it does not, the statute should be given its intended meaning.

This Court has repeatedly sanctioned federal regulation of intrastate activities where such regulation is appropriate to the effective and successful regulation of commerce. See *United States* v. *Wrightwood Dairy Co.*, 315 U. S. 110, 119; *Wickard* v. *Filburn*, 317 U. S. 111, 124; *United States* v. *Darby*, 312 U. S. 100, 118–122. In the *McDermott* case, the label under which a food moved in interstate commerce was protected, even against state action, after the product had reached the retailer's shelves awaiting sale to ultimate consumers. The situation is no different here. The drug in question had moved in interstate commerce under the sanction of the federal law because it was not misbranded. When it reached the retailer's shelf, acts were done which constituted an obvious misbranding of the drug. The purpose of the Food, Drug, and Cosmetic Act is to prevent goods shipped in interstate commerce from harming consumers. As this Court said in *United States* v. *Dotterweich*, 320 U. S. 277, 280, "The purposes of this

legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection." If, after the federal government has permitted a drug to be shipped in interstate commerce, the local seller may destroy the protective label which the federal government required or otherwise misbrand the product, the purpose of the Act will be defeated. The reason for requiring proper labels will be frustrated and the ultimate consumer will be deprived of the protections the Act was designed to safeguard. See *McDermott* v. *Wisconsin*, 228 U. S. 115, 130–131. The decision below allows the local dispenser the advantages of interstate distribution under unquestionably valid conditions prescribed by Congress in order to obtain the products he deals in, but permits him to nullify the very conditions under which the interstate shipment was sanctioned by misbranding the product before it reaches the ultimate consumer, for whose benefit the Act exists. The obvious intendment of Section 301 (k) was to prevent such acts of misbranding as an appropriate means fully to effectuate the purpose of the Act to protect the consuming public by closing the channels of interstate commerce to deleterious and misbranded foods and drugs.

We submit that the commerce power does permit the federal government to insist that when a

drug is permitted to move in commerce on condition that it is not misbranded, the condition shall not be subverted thereafter by misbranding the product before it reaches the ultimate consumer,

2. We are advised by the Administrator of the Act that the views expressed here have been adhered to consistently in the administration of the Act. Regulations relating to the movement in interstate commerce of numerous foods and drugs have been framed on the assumption that Section 301 (k) forbids a retailer from misbranding a product which has moved in interstate commerce. An extensive enforcement program has been carried out to insure compliance with Section 301 (k). The adverse effect which the decision below, if it is not reversed, will have on the enforcement of the Federal Food, Drug, and Cosmetic Act and on the protection to consumers contemplated by it is illustrated by the following examples which have been suggested by the Administrator.

a. Considerable success has been had in the enforcement of Section 502 (a) of the Act so as to eliminate from drugs and devices false and misleading claims of their efficacy in the treatment of ailments, such as cancer, tuberculosis and diabetes. The salutary effect of such enforcement may be completely dissipated if the first intrastate purchaser can, with impunity, relabel the articles

with the same false and exorbitant claims which the act has outlawed.

b. Section 502 (d) requires that the statement, "Warning—May be habit forming," appear on certain drugs; Section 502 (f) (1) and (2) require adequate directions for use and warnings against misuse. If a local dealer may remove these labels with impunity, the statutory provisions are requirements which exist only to be frustrated.

c. There are some drugs, as in this case, for which adequate directions for lay use cannot be devised. These drugs should be dispensed only on prescriptions by physicians. Regulations promulgated under Section 502 (f) (1) have exempted such drugs from bearing adequate directions for use, and have required such drugs to bear the "prescription legend" (*supra*, pp. 4–5, 7). It was contemplated that such drugs would be sold only on prescription, and the regulations were based on the assumption that Section 301 (k) could be invoked to protect the label on the drugs while they are held for sale after shipment in interstate commerce. The decision below removes this protection.

d. The regulations which have been promulgated under the Act with respect to insulin, penicillin, and streptomycin have been based on the assumption that Section 301 (k) reaches the act of misbranding while these drugs are held for

sale. In a letter to the Speaker of the House of Representatives, dated January 22, 1947, recommending the passage of a bill providing for the certification of drugs composed wholly or partly of streptomycin, the Federal Security Administrator advised the Congress, *inter alia*, of the Administrator's reliance on Section 301 (k). See H. Rep. No. 75, 80th Cong., 1st sess.; see also a similar letter sent to the Chairman, Senate Committee on Interstate and Foreign Commerce, on February 25, 1947, S. Rep. No. 45, 80th Cong., 1st sess.

e. With respect to food, the evils are also great. In recent years, the Administrator of the Act has initiated actions under Section 301 (k) for false rebranding of horse meat as beef; of cottonseed and soybean oils as olive oil; of imitation black pepper as pure pepper; of imitation orange beverage as pure orange juice; of Japanese crab meat as Russian crab meat; of domestic cheese as imported cheese; and of shrimp canned without federal inspection as shrimp canned under federal inspection. Under the decision below, any of these acts by one who is not the importer would be beyond the reach of federal control.

CONCLUSION

The question presented is one of great importance in the administration of the Federal Food, Drug, and Cosmetic Act. The decision

below limits the plain words of Section 301 (k) beyond their fair meaning and the evident congressional purpose, because of the court's doubts as to the constitutionality of a broader construction. Only this Court can finally resolve the constitutional question. We therefore respectfully submit that this petition for a writ of certiorari should be granted.

GEORGE T. WASHINGTON,
Acting Solicitor General.

JUNE 1947.

U. S. GOVERNMENT PRINTING OFFICE: 1947

No. 121

In the Supreme Court of the United States

OCTOBER TERM, 1947

UNITED STATES OF AMERICA, PETITIONER

v.

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY

ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES

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OPINIONS BELOW

The opinion of the circuit court of appeals (R. 58–63) is reported at 161 F. 2d 629. The opinion of the district court (R. 11–27) is reported at 67 F. Supp. 192.

JURISDICTION

The judgment of the circuit court of appeals was entered May 12, 1947 (R. 63). The petition for a writ of certiorari was filed June 10, 1947, and was granted October 13, 1947. The jurisdiction of this Court is conferred by Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925. See also Rules 37 (b) (2) and 45 (a), F. R. Crim. P.

QUESTIONS PRESENTED

1. Section 301 (k) of the Federal Food, Drug, and Cosmetic Act prohibits the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to," a drug, if such an act is done while "such article is held for sale after shipment in interstate commerce and results in such article being misbranded." The question is whether this provision extends to a retail druggist who has purchased a drug shipped interstate from a wholesale source in the same state and who then misbrands the drug after it has reached his shelves.

2. If so, whether Section 301 (k) is a constitutional exercise of the commerce power.

STATUTE AND REGULATION INVOLVED

The Federal Food, Drug, and Cosmetic Act, June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, et seq.), provides in pertinent part:

> SEC. 301. The following acts and the causing thereof are hereby prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. [21 U. S. C. 331 (a).]
>
> (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce. [21 U. S. C. 331 (b).]

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. [21 U. S. C. 331 (c).]

* * * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded. [21 U. S. C. 331 (k).]

* * * * *

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine. [21 U. S. C. 333 (a).]

* * * * *

SEC. 502. A drug or device shall be deemed to be misbranded—

* * * * *

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. [21 U. S. C. 352 (c).]

* * * * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods of duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement. [21 U. S. C. 352 (f).]

Regulation 2.106 (b) promulgated by the Acting Administrator on April 10, 1941, 6 Fed. Reg. 1920, provides:

(b) A shipment or other delivery of a drug or device shall be exempt from com-

pliance with the requirements of clause (1) of section 502 (f) of the Act if:

(1) Such shipment or delivery is made for use exclusively by or on the prescription of physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device;

(2) Adequate directions for so using such drug or device are available in scientific publications or otherwise;

(3) The label of such drug or device bears the statement "Caution: To be used only by or on the prescription of a ----------", or "Caution: To be used only by a ----------", the blank to be filled in by the word "Physician", "Dentist", or "Veterinarian", or any combination of two or all of such words, as the case may be;

(4) No representation appears in the labeling of such drug or device with respect to the conditions for which it is to be used; and

(5) In the case of a drug which is not designated solely by a name recognized in an official compendium and which is fabricated from two or more ingredients, its label also bears the quantity or proportion of each active ingredient.

Such exemption shall remain valid until all of such shipment or delivery is used by physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device, or is dispensed upon, and under labels bearing the directions for use specified in,

prescriptions of such physicians, dentists, or veterinarians. But if such shipment or delivery, or any part thereof, is otherwise disposed of as a drug or device, such exemption shall thereupon expire. The causing by any person of such an exemption so to expire shall be considered to be an act of misbranding for which such person shall be liable unless, prior to such disposition, such drug or device is relabeled to comply with clause (1) of section 502 (f) of the Act.

* * * * *

STATEMENT

On December 31, 1945, an information in two counts (R. 2–8) was filed in the United States District Court for the Middle District of Georgia charging respondent with violations of the Federal Food, Drug, and Cosmetic Act. Each count alleged that a bottle containing sulfathiazole tablets was shipped in interstate commerce from North Chicago, Illinois, to Atlanta, Georgia; that the bottle was then sold to respondent with the same label as when shipped in interstate commerce; that on a specified occasion, while respondent held the drug for sale in his drug store, he removed 12 tablets from the bottle, repacked them in a box bearing on the label only the name of the drug, and sold them; that the drug, as so repacked and sold, did not bear adequate directions for use as required by Section

502 (f) (1) of the Act and did not bear certain warnings required by Section 502 (f) (2) of the Act; and that the drug was thus misbranded, in violation of Section 301 (k) of the Act.[1]

On February 8, 1946, respondent filed a motion to dismiss the information (R. 10), in which he urged that no offense was charged; that his acts were not in interstate commerce and were thus beyond the power of Congress to regulate; that properly construed, Sections 301 (k) and 502 (f) (1) and (2) apply only to misbranding in interstate commerce; and that if Section 301 (k) were construed to apply to respondent's acts, it is unconstitutional and in violation of the Tenth Amendment. On June 19, 1946, the district court filed an opinion (R. 11–27) rejecting respondent's contentions.

Regulation 2.106 (b), under the Food, Drug and Cosmetic Act (*supra*, pp. 4–6) permits the shipment of various drugs in interstate commerce without appropriate instructions as to use if the drug is labeled with the prescription legend—"Caution: To be used only by or on the prescription of a physician"—and if various other specified conditions are satisfied. The regulation is designed to deal with those drugs for which adequate directions for lay use cannot be devised.

[1] Each count related to a separate transaction. The first count charged the respondent with causing the doing of the prohibited act. The second count alleged that respondent performed the act.

As we show below, it was pursuant to this regulation that the drug in this case was shipped in interstate commerce.

Respondent waived a jury trial (R. 28). The undisputed evidence at the trial showed that during the period between November 25, 1943, and March 15, 1944, Abbott Laboratories shipped to itself at Atlanta, Georgia, bottles containing 1,000 tablets of sulfathiazole and bearing a warning that the tablets were to be "used only by or on the prescription of a physician." (R. 29–30, 31, 34.)[2]

Respondent purchased one of these bottles in Atlanta, and it was shipped to him at Columbus,

[2] The label on the bottle which was shipped in interstate commerce and from which the 12 tablets were removed in each instance read as follows (see R. 3, 29):

"1,000 Tablets (Bisected)
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Georgia, where he operated a retail drug store (R. 29). On December 13, 1944, an inspector of the Food and Drug Administration purchased, without a doctor's prescription, 12 sulfathiazole tablets from respondent's drug store (R. 32). On the following day another inspector made a similar purchase (R. 38). In both instances, immediately prior to the sale, the tablets which were sold were removed from the container in which they were shipped and which bore the warning against their use without a physician's prescription; they were placed in small containers on which only the name of the drug—sulfathiazole—appeared (R. 29, 32, 35–37, 38).

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SPECIFICATION OF ERRORS TO BE URGED

The circuit court of appeals erred:

1. In reversing the judgment of the district court.

2. In holding that the act of a retailer in removing a drug, which he held for sale after shipment in interstate commerce, from its properly labeled interstate container and placing it in another container without appropriate labeling is not a violation of Section 301 (k) of the Federal Food, Drug, and Cosmetic Act.

SUMMARY OF ARGUMENT

I

A. Section 301 (k) prohibits the misbranding of a product "while such article is held for sale after shipment in interstate commerce." Respondent's conduct clearly comes within these words. There is no basis in the statute for the action of the court below limiting the above language to the first sale after interstate commerce. Indeed, the court below recognized that the first clause of paragraph (k), which prohibits the "alteration, mutilation * * * or removal * * * of the labeling" could be applied to "anyone" who at any time destroys the interstate label (R. 60–61). But the same qualifying words, "held for sale after shipment in interstate commerce" necessarily mean the same thing when applied to the second clause of paragraph (k). The same words in the same paragraph cannot be accorded two different meanings.

The structure of Section 301 reflects an effort by Congress to protect the public, to the extent that it may constitutionally do so, at each stage of the movement of goods from their initial entry into the stream of commerce until they finally reach the consumer. Paragraphs (a), (b) and (c) prohibit the initial introduction into commerce of misbranded products, the misbranding of the product while it is in commerce, and the receipt in commerce and delivery of a misbranded product. If Congress had intended that paragraph (k) should apply only to the interstate importer, who is also reached by paragraph (c), apt words were available to accomplish this result. Significantly, the House Committee on Interstate and Foreign Commerce has recommended the addition to Section 301 (k), as a clarifying amendment to overcome the result of the decision below and conform to the original legislative intention, of the parenthetical phrase "whether or not the first sale."

B. There is nothing in the well-known purposes of the statute which justifies the confining construction of Section 301 (k) which the court below adopted. The Act on its face, as well as in its legislative history, demonstrates that its purpose is to protect *the consumer* against adulterated or misbranded foods, drugs and cosmetics which come through the channels of commerce. This Court has often so recognized. The committee report as to Section 301 (k) states that it

is intended "to extend the protection of consumers contemplated by law to the full extent constitutionally possible." H. Rep. No. 2139, 75th Cong., 3rd sess. This purpose will be substantially defeated if Section 301 (k) is subjected to the interpretation adopted by the court below. For under that decision the retailer can escape the federal regulation by arranging to purchase from an intra-state wholesaler or jobber, and by transferring articles to an improperly labeled container. Proper labeling is the only protection the consumer has from the serious dangers which likely will result from the use of drugs not in accordance with the cautionary warnings and directions required by the Act for the consumer's benefit.

II

The constitutional question which the court below sought to avoid (see R. 62) is whether Congress, to accomplish its primary purpose of protecting the consumer to the full extent of its constitutional power, may protect the interstate label or brand from misbranding after the article has reached the retailer and is held for sale by him. If, as we believe, protection of the label at the retail level is essential to the accomplishment of the objective of Congress in regulating the shipment of foods and drugs in commerce, the fact that Congress is regulating an intrastate act presents no constitutional obstacle. This Court

has sanctioned such regulation many times. See *Wickard* v. *Filburn,* 317 U. S. 111, 124; *United States* v. *Walsh,* 331 U. S. 432, 437. Only by the means which Congress has adopted can there be any assurance that the object of the regulation of the label in interstate commerce—consumer protection—will be achieved.

Section 301 (k) is a statutory embodiment of this Court's decision in *McDermott* v. *Wisconsin,* 228 U. S. 115, wherein the Court denied a state the right to require a local retailer to remove the interstate label on a product which he held for sale. The rationale of that decision demonstrates that to accomplish the statutory objective Congress must have the power to control the labeling until the article reaches the ultimate purchaser for whom the label is intended. In this respect, we perceive no constitutional difference between forbidding misbranding by removing the label, as in the *McDermott* case, and forbidding accomplishment of the same thing by removing the article from its properly labeled container and placing it in a mislabeled one, as in this case. Congress certainly must possess the power to prohibit the one as much as the other.

Section 301 (k) is not novel. Congress has in many other statutes legislated to protect the label under which a product moves in interstate commerce from misbranding while held for sale to the consumer. In the many years that such

statutory provisions have existed they have been challenged only once, and in that case the court explicitly held that Congress had the power to protect the interstate label while the product was held by a retailer for sale to the ultimate consumer. *United States* v. *Ury*, 106 F. 2d 28 (C. C. A. 2). This Court should be reluctant to overturn the repeated Congressional judgment that the means which it has adopted are essential to the accomplishment of its purpose.

ARGUMENT

INTRODUCTION

In *McDermott* v. *Wisconsin*, 228 U. S. 115, decided in 1913, this Court held that the Food and Drugs Act required the Federal label to be kept on products while they were held for sale on a retailer's shelves. Congress has since enacted a number of laws which have required the correct branding of products shipped in interstate and foreign commerce until they reached the ultimate consumer. The validity of these statutes has been challenged only once and then unsuccessfully.

The question here is not only whether Section 301 (k) of the Food, Drug, and Cosmetic Act of 1938 is valid but whether Congress has been incorrect in all of this legislation in assuming that it had power to protect the consumer against the misbranding of articles shipped across state lines

while they are held for sale at retail. Because of its doubts as to this constitutional issue, the court below construed Section 301 (k) as not reaching such acts by a retailer who is not the interstate importer—although the language, purpose, and history of the Section clearly forbade any such limited construction. It is the Government's position that the court below erred in not giving Section 301 (k) the construction required by its terms, and that the Section is constitutional if it is construed as Congress intended.

I

SECTION 301 (K) PROHIBITS THE MISBRANDING OF DRUGS WHILE THEY ARE HELD FOR SALE BY A RETAILER TO THE ULTIMATE CONSUMER

A. The language of the statute

Section 301 of the Food, Drug, and Cosmetic Act (52 Stat. 1042, 21 U. S. C. 331) provides:

> The following acts and the causing thereof are hereby prohibited:
>
> * * * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done *while such article is held for sale after shipment in interstate commerce*[3] and results in such article being misbranded.

[3] All italics used throughout the brief have been added.

It has not been, nor can it be, contended that the boxes of tablets sold by respondent were not misbranded under the Act and the regulations.[4]

The question raised by this case is whether Paragraph (k) extends to goods held by the retailer for sale to the ultimate consumer after shipment of the goods in interstate commerce to the wholesaler from whom the retailer purchased them. Respondent argued below that the Para-

[4] Section 502 (f) of the Act (52 Stat. 1051, 21 U. S. C. Sec. 352 (f)), declares that a drug shall be deemed to be misbranded "Unless its labeling bears (1) adequate directions for use", and permits the Administrator to promulgate regulations exempting drugs from this requirement when its observance "is not necessary for the protection of the public health". The Administration has issued regulations which exempt drugs from the requirement as to directions for use if and while they bear the "prescription legend" stating that they are to be used only by or on the prescription of a physician (or dentist, or veterinarian). See pp. 4–6, *supra*. The tablets sold by respondent were placed in a container which did not bear either the prescription legend or any directions for use, but merely the word "sulfathiozole." The label thus was clearly a misbranding within the meaning of Section 502 (f). The placement of the tablets in the misbranded boxes was equally clearly the "doing of any other act with respect to, a " * * * drug * * * [which] results in such article being misbranded", under Section 301 (k). Indeed, the trial court held that the acts of removing the tablets from a properly labeled container to the improperly labeled boxes "are in fact alteration or obliteration of part of the label" within the meaning of the first clause of Section 301 (k) (R. 24). The circuit court of appeals conceded that the portion of the drug placed in the boxes "became misbranded" (R. 60), and did not suggest that respondent's conduct would have been lawful if respondent had purchased the tablets directly from outside of the state.

graph should not be construed as extending to misbranding in intrastate commerce, but did not make any suggestion as to what the phrase italicized above could mean if the Paragraph were so limited. The court below held that the Paragraph applied "only to the holding for the first sale by the importer after interstate shipment" (R. 60), but then seemingly qualified its interpretation of "held for sale after shipment in interstate commerce" by observing that "the United States can prohibit the destruction of the labeling under which interstate commerce occurred, by anyone at any time, in order to preserve the evidence of what was done during the interstate movement" (R. 60–61). Although it is not clear, the inference from the opinion is that Paragraph (k) can properly be applied to such methods of tampering with the label even after the first sale.

The precise issue here is whether the clause "while such article is held for sale after shipment in interstate commerce" covers the conduct of respondent. Here the transactions occurred after shipment in interstate commerce and while the tablets were held for sale. There can be no question that they come within the plain and unequivocal language of the statute. The opinion below seems to concede this (R. 60). To interpret the clause as applying only to an act of misbranding by the original importer, while the goods were held for the *first sale* after interstate

shipment, is to read into the statute words which are not there.

Furthermore, the structure of Section 301 reflects an effort by Congress to protect the public, to the extent that it may constitutionally do so, at each stage of the movement of food and drugs from their initial entry into the stream of commerce until they finally reach the consumer. Section 301 (a) prohibits "the introduction or delivery for introduction into interstate commerce" of any misbranded or adulterated food, drug, device or cosmetic. The second stage is reached by Section 301 (b), which prohibits the misbranding, adulteration of any such item while "in interstate commerce." Section 301 (c) proscribes the "receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery of proffered delivery thereof for pay or otherwise."

Paragraph (c) carries the protection against misbranding of goods shipped interstate as far as the original importer by making it unlawful for him to receive and to deliver or offer to deliver such merchandise. Paragraph (k) then goes beyond Paragraph (c) to reach misbranding by anyone if an article is held for sale after interstate shipment. Clearly if Congress had meant to limit Paragraph (k) to the importer, more apt—and certainly less sweeping—words would have been chosen for that purpose.

That Section 301 (k) was not intended merely to reach the importer is confirmed by legislative events which have occurred since the decision below. During hearings on June 12, 1947, before a subcommittee of the House Committee on Interstate and Foreign Commerce on H. R. 3128 and H. R. 3147, with respect to a proposed amendment to Section 304 (a) of the Act, reference was made to the decision below in this case (pp. 7–9). The Committee thereupon recommended in its report (H. Rep. No. 807, 80th Cong., 1st Sess.) that Paragraph (k) be amended by insertion of the parenthetical phrase "whether or not the first sale" after the words "while such article is held for sale". The Report states specifically that—

> The insertion of the parenthetical wording "(whether or not the first sale)" in section 301 (k) is not designed to change the original intended meaning of the section but would simply make it entirely clear that "held for sale" includes the first sale and any subsequent sale. * * *[5]

[5] The Committee Report then continues: "As a result of a decision on May 12, 1947, by the Circuit Court of Appeals for the Fifth Circuit, in the case of *Jordan J. Sullivan* v. *United States*, doubts have arisen as to the ultimate judicial interpretation of the present language. Language similar to the present language occurs in other congressional enactments, such as the Federal Seed Act of 1912, as amended in 1926 (44 Stat. 325, 326; 7 U. S. C. 116 (b). (2)); the Federal Caustic Poison Act (44 Stat. 1406, 1408; 15 U. S. C. 404); and the Federal Alcohol Administration Act (49 Stat. 977, 983; 27 U. S. C. 205 (e)). The insertion of the parenthetical

The proposed amending bill is presently pending before the Congress. But this statement of the Committee responsible for food and drug legislation is a strong indication that the decision of the court below is not in accord with the original congressional intention. It is also to be noted that the same Committee approved an amendment to Section 507 of the Act (Act of March 10, 1947, Pub. L. No. 16, 80th Cong., 1st Sess.) so as to include streptomycin as well as penicillin upon the basis of a letter from the Federal Security Administrator which stated, *inter alia,* that under Section 301 (b) the drug would be protected while it was in interstate commerce and that under Section 301 (k) the protection would extend until the drug "was ultimately sold for use". See pp. 30–32, *infra.*

An additional reason for rejecting the construction of the statute adopted by the court below is the peculiar situation which acceptance of that interpretation would create. In the first place, it is to be noted that construing the paragraph as limited to the importer would not exempt all retailers, since a retailer who purchased directly from out-of-state sources would still be covered. But more significantly, the court below seems to concede that the first clause of Paragraph (k) which prohibits the "alteration, mutilation * * *

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clause by the amendments here under consideration is not intended to be taken as a reason for restricting the scope or meaning of these earlier enactments."

or removal * * * of the labeling" could be applied to "anyone" who "at any time" destroys the interstate label (R. 60–61). This concession was probably motivated by the fact that the court had no doubt as to the constitutionality of such an application of the Act under the *McDermott* case discussed *infra*, pp. 39–41. But the phrase "held for sale after shipment in interstate commerce" cannot have one meaning with respect to the offenses described in the first clause of Paragraph (k) and another with respect to those in the second clause. For the crucial words occur but once in the Paragraph and obviously mean the same thing as applied to each of the two clauses which precede them.

Furthermore, the district court found that the acts in question here constituted an "alteration or obliteration" of a label in violation of the first clause as well as "any other act" causing misbranding in violation of the second clause (R. 24). It would be anomalous to overturn this holding on the ground that Paragraph (k) reaches acts by any retailer which physically affect the interstate label, but only acts by the original importer if the same misbranding is accomplished by transferring the contents of a properly labeled container to an improperly labeled one. And yet that is what we believe the court below held.

B. The purpose of the statute

Nothing in the legislative history or well known purposes of the statute suggests that Section 301 (k) was not intended to mean what it says. On the contrary, they show that the Paragraph must be given a literal construction if the statute is to accomplish its objectives.

The purpose of the statute, as disclosed on its face as well as by its legislative history, is to protect *the consumer* against adulteration or misbranding of foods, drugs, and cosmetics, which come through the channels of interstate commerce. As this Court has noted, "The House Committee reported that the Act 'seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906.' (H. Rep. No. 2139, 75th Cong., 3d Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation 'must not weaken the existing laws,' but on the contrary 'it must strengthen and extend that law's protection of the consumer.' (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1.)" *United States* v. *Dotterweich,* 320 U. S. 277, at 282. The House Report also declared that "the old law * * * is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions". And with respect to labeling, the Report explicitly stated that "Informative

labeling of foods as to quality and composition is required for the information and guidance of consumers".

In this setting, and in the light of these objectives, Paragraph (k)[6] was added to Section 301 by the House Committee. In explanation the Committee Report stated:

> * * * In general this section denies the channels of interstate commerce to products which are adulterated or misbranded or are otherwise unsafe for use. It order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment.

That the protection of consumers is the objective of the statute also appears from Section 401 (21 U. S. C. 341), dealing with food, and Section 502 (c) (21 U. S. C. 352 (c)), which relates to drugs. The former twice defines the criterion which is to guide the Administrator in establishing definitions and standards for food as the promotion of "honesty and fair dealing *in the interest of consumers.*" With respect to drugs,

[6] The subsection was inserted in the bill while it was pending before the committee, and so far as we know the quoted language is the only specific reference to the provision in the legislative history of the Act.

Section 502 (c) makes the test of proper branding whether information placed on the label is

> prominently placed thereon with such conspicuousness * * * and in such terms as to render it likely to be read and understood *by the ordinary individual under customary conditions of purchase and use.*

In many decisions this Court and other federal courts have also recognized that consumer protection is the ultimate statutory goal. In *McDermott* v. *Wisconsin,* 228 U. S. 115, the Court observed that this object would be defeated if the lawful label were not placed on the container which actually reached the consumer; the opinion states in this connection (pp. 130–131):

> * * * Within the limitations of its right to regulate interstate commerce, Congress manifestly is aiming at the contents of the package as it shall reach the consumer, for whose protection the act was primarily passed, and it is the branding upon the package which contains the article intended for consumption itself which is the subject-matter of regulation. Limiting the requirements of the act as to adulteration and misbranding simply to the outside wrapping or box containing the packages intended to be purchased by the consumer, so that the importer, by removing and destroying such covering, could prevent the operation of the law on the

> imported article yet unsold, would render the act nugatory and its provisions wholly inadequate to accomplish the purposes for which it was passed.
>
> The object of the statute is to prevent the misuse of the facilities of interstate commerce in conveying to and placing before the consumer misbranded and adulterated articles of medicine or food, and in order that its protection may be afforded to those who are intended to receive its benefits the brands regulated must be upon the packages intended to reach the purchaser. * * *

The same theme recurs in subsequent decisions. "The purpose of the act is to secure the purity of food and drugs and to inform purchasers of what they are buying. Its provisions are directed to that purpose and must be construed to effect it." *United States* v. *Antikamnia Co.*, 231 U. S. 654, at 665. "The legislation, as against misbranding, intended to make it possible that *the consumer should know* that an article purchased was what it purported to be * * *." *United States* v. *Lexington Mill Co.*, 232 U. S. 399, at 409. "* * * the legislative history of the statute manifests the purpose of Congress to substitute, for informative labeling, standards of identity of a food, sold under a common or usual name, so as to give *to consumers who purchase it under that name assurance* that they will get what they

may reasonably except to receive. * * *" *Federal Security Adm'r.* v. *Quaker Oats Co.*, 318 U. S. 218, at 232. "Here, *the consumer* would be unaware that less expensive ingredients had been substituted and that the article was inferior to that which he expected to receive when making his purchase. The fact that the substituted article was not deleterious is immaterial. From its inception, to its last amendment, the Pure Food and Drugs Act was * * * intended to protect the consuming public." *United States* v. *Two Bags, Etc.*, 147 F. 2d 123, at 127 (C. C. A. 96). "* * * it is manifest that misbranding has true significance only in terms of *the consumer* * * *." *United States* v. *7 Jugs, Etc. of Dr. Salsbury's Rakos*, 53 F. Supp. 746, at 754 (D. Minn.).

There can thus be no question that the purpose of the Act, and of Section 301 (k), in particular, is, in the language of the Committee Report "to extend the protection of consumers contemplated by the law to the full extent constitutionally possible."

This purpose will be, to a considerable extent, defeated if Section 301 (k) is subjected to the confining construction placed upon it by the court below. For although the statutory scheme is directed at the use of accurate labeling which "the ordinary individual under customary conditions of purchase and use" can "read and" under-

stand (Section 502 (c), 21 U. S. C. 352 (c)), such a limiting construction of the statute would mean that the protection of the law disappeared before the product reached the person for whom the accurate labeling was intended.

Under the decision below, goods held for sale to ultimate consumers by retailers who purchase the articles directly from outside the state would be covered. But undoubtedly a large proportion of food, drugs and cosmetics is purchased by retailers from wholesalers within the same state.[1] And any retailer who is disposed not to comply with the statute could see to it that he obtained his supplies from wholesalers in his state, whether he otherwise would have done so or not.

The same situation would prevail as to that portion of the opinion below which indicates that, on the one hand, retailers can not lawfully alter the actual labels which have arrived through the channels of interstate commerce, but that they can with impunity remove the articles to an improperly labeled container. Retailers who are disposed not to label their products accurately, or to sell dangerous drugs without a prescription—and it is only against such retailers that

[1] Only about 20% of the drugs manufactured are sold directly by the manufacturer to the retailer, while more than two-thirds are sold first to wholesalers or jobbers. The remainder are sold directly to professional or industrial users or are exported. See 5 Census of Business, 1939, table 1, p. 95; 2 Standard and Poor's Trade and Securities, p. D 1–4.

the public needs to be protected—would find that the opinion below created a wide loophole in the statutory scheme.

The injury to the public health which may result if the protection of the statute is lifted before the articles reach the ultimate consumer is particularly serious insofar as drugs are concerned. Many drugs which are extremely useful in curing disease are also extremely dangerous. Such drugs include the sulfonamides, which are powerful chemo-therapeutic agents; the barbiturates, which have hypnotic properties; thyroid, which may increase the metabolic rate; streptomycin, a new anti-biotic drug; digitalis, which has a profound effect on heart action; thiouracil, which is useful in the treatment of hyperthyroidism but which has the ability to destroy the body's capacity to produce white blood cells; benzedrine, a stimulant for the central nervous system which when used unwisely is followed by total collapse; insulin, for the treatment of diabetes but which causes severe shock when used in overdosage; thiocyanates, which are useful in treating hypertension but may result in vascular collapse; and curare, which causes relaxation of the muscles but may result in total paralysis and death.

While Congress undoubtedly did not intend to exclude such drugs from interstate commerce, it did mean to condition their interstate movement on compliance with regulations which would safeguard the public health.

Section 502 (f) and the regulations promulgated thereunder (see pp. 4–6, *supra*) provide that a drug shall be deemed misbranded "Unless its labeling bears (1) adequate directions for use", or, in the alternative, the prescription legend stating that the drug is to be used only on the prescription of a physician.[8] If these provisions do not extend to the product while it is held for sale at retail, unscrupulous druggists can deprive the public of the protection which the Act was designed to establish for all drugs which have moved in interstate commerce.

This case itself affords an excellent illustration. It involves sulfathiazole, a drug which is well known to have profound physiological effects even when used under a physician's care. The dangers to the public health which will result if such a drug can be sold indiscriminately without adequate directions are obvious.[9] Here the lawful

[8] As to the drugs referred to above, directions adequate for use by the layman could hardly be devised; their safe and efficacious use requires the supervision of a physician.

[9] Medical literature dealing with the serious complications which may result from the use of the drug abundantly illustrates this fact. See e. g., Garvin, "Complications Following the Administration of Sulfanilamide," 113 Journ. American Medical Association 228–291 (1939); Corr and Root, "Death From Granulocytopenia After Sulfanilamide Therapy," 112 Journ. American Medical Association 1939–1940 (1939); Reinhold, Flippin and Schwartz, "Observations On The Pharmacology And Toxicology Of Sulfathiazole In Man," 199 American Journal of The Medical Sciences 393–401 (1940); Bigler and Haralamibie' "Sulfanilamide And Related Compounds," 57 American Journal of Diseases of Children 1110, 1119–1128 (1939).

label placed upon the jar containing the tablets by the manufacturer stated not only that the tablets were to be used only on the prescription of a physician, but also included a warning (R. 3, 29) that

> In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

When respondent sold the tablets both the prescription legend and the warning were deleted.

There are other instances wherein the public health would be jeopardized by a denial of the full sweep of Section 301 (k). Drugs containing insulin, penicillin, or streptomycin cannot legally move in interstate commerce unless, pursuant to regulations promulgated by the Administrator under Sections 506 and 507,[10] they are pretested and certified by the Food and Drug Administration. The plan of control of these drugs is designed to insure their safety and efficacy in the treatment of numerous diseases. Among other things the statute requires that the labeling of a certified batch must bear an expiration date beyond which the drug is deemed not to be fully

[10] These sections were added to the statute in 1941 and 1945. See 55 Stat. 851, 59 Stat. 463, 21 U. S. C. Supp. V, 352 (k) (l) 356, 357.

potent."[11] It had been assumed by the Federal Security Agency, justifiably we believe, that any dealer, including retail druggists, who did any act with respect to such a drug which would falsify or remove this expiration date was subject to prosecution under Section 301 (k). In a letter to

[11] H. Rep. 1542, 77th Cong., 1st sess., accompanying H. R. 6251 which became Section 506, contained the following statement from the Committee on Interstate and Foreign Commerce: "Each user of insulin must learn through his physician the quantity and frequency of dosage necessary for him. Most diabetics subsequently buy their insulin direct from drug stores and administer it to themselves with only occasional checkups by physicians. If the drug is too strong, insulin convulsions may follow and even death. If it is too weak, coma may result from which the patient may not recover. Such results are particularly likely if he is relying upon himself alone for the administration of the drug. With no other drug are the consequences of failure of accurate standardization so dramatic and so immediate.

* * * * *

"* * * Inasmuch as over-age or improperly packaged or labeled insulin is unsafe, such certificates are to be effective only for periods prescribed in the regulations, and the certified batches and drugs therefrom are to be protected by such certificate only for the prescribed period, or for such part thereof as such drug meets the labeling and other requirements prescribed in such regulations for the protection of the public."

See also S. Rep. 410, 79th Cong., 1st sess., accompanying H. R. 3266; and S. Rep. 45, 80th Cong., 1st sess., accompanying S. 445, which became the penicillin and streptomycin amendments to the Act. The reports emphasize the importance, in terms of the public health, of preventing the distribution to consumers of these drugs after the expiration date of effective certificates or in containers that do not bear the required labeling.

the Speaker of the House of Representatives[12] dated January 22, 1947 (see H. Rep. No. 75, 80th Cong., 1st sess.) recommending passage of the Act of March 10, 1947, Pub. L. No. 16, 80th Cong., 1st sess., so as to include streptomycin as well as penicillin, the Federal Security Administrator said:

> The extreme rarity with which uncertified insulin or penicillin is introduced into interstate commerce demonstrates that the certification procedure substantially insures that drugs subject to it are what they ought to be when their interstate movement begins. The provision of the act in section 301 (b), which prohibits the adulteration or misbranding of an article while in interstate commerce, tends to safeguard the product during that time. Likewise, the provision of the act in section 301 (k), prohibiting the doing of any act with respect to an article while it is being held for sale after interstate shipment if such act results in the misbranding of the article, tends to extend protection until it is ultimately sold for use. (It will be noted that uncertified insulin and penicillin are defined in section 502 (k) and (l) as misbranded.)

It was in large part upon the basis of the explanation contained in this letter that Congress passed the streptomycin amendment (see H. Rep.

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[12] A similar letter was sent to the Chairman, Committee on Interstate and Foreign Commerce on February 25, 1947 (S. Rep. No. 45, 80th Cong., 1st sess.).

No. 75, 80th Cong., 1st sess.; S. Rep. No. 45, 80th Cong., 1st sess.).

We think it clear that the public health which the statute seeks to protect would be imperiled if the statutory provision against misbranding of drugs became inoperative before the goods shipped in interstate commerce were sold to the ultimate consumer. Accordingly, we submit that the purpose as well as the language of Section 301 (k) requires that it be construed so as to reach misbranding occurring at that stage of the distribution process.

It is apparent from the opinion below that the circuit court of appeals would not have given to the statute a narrower construction if it had not thought that a literal interpretation would have been unconstitutional. In Point II we shall show that Section 301 (k) would not be invalid if it is interpreted in the manner which its words, history and purpose all combine to require.

II

THE UNDISPUTED POWER OF CONGRESS TO REQUIRE A PROPER LABEL ON A DRUG WHICH MOVES IN INTERSTATE COMMERCE EXTENDS TO THE PROTECTION OF THAT LABEL UNTIL THE PRODUCT REACHES THE ULTIMATE CONSUMER. THIS IS AN APPROPRIATE MEANS FOR ACHIEVING THE OBJECTIVE OF CONGRESS IN REQUIRING THAT DRUGS BE PROPERLY LABELED

The constitutional question which the circuit court of appeals sought to avoid (see R. 62) is whether Congress, to accomplish its primary purpose of protecting the consumer to the full extent of its constitutional power, may protect the label

or brand by which a product moves in interstate commerce from misbranding after the article has reached the retailer and is held for sale by him. In other words, may Congress in the exercise of the commerce power confer on the consumer the right to know that the drug which he purchases from the local drug store moved in interstate commerce labeled with specified warnings and directions for use; or that the canned food which he purchases in the local grocery store moved in interstate commerce as standard or substandard merchandise;[13] or that the meat product which he purchases passed federal inspection; or that the clothing which he purchases was manufactured from material containing only a specified amount of virgin wool; or that the imported article which he purchases from a local store was produced in a specified country.

The test in determining the validity of Section 301 (k) is, of course, not whether the drugs are still in interstate commerce at the time the federal statute is sought to be applied. This Court has frequently held that intrastate transactions can be regulated under the Commerce Clause, and that it is immaterial whether such acts are part of "production" or "consumption" or "marketing" or of a "local character". *Wickard* v. *Filburn*, 317 U. S. 111, 124. The intrastate

[13] See, e. g., Definitions and Standards of Quality for Canned Green Beans and Canned Wax Beans, promulgated February 19, 1947, 12 Fed. Reg. 1137, 1140–1141.

operations of the Chicago milk dealer in *United States* v. *Wrightwood Dairy*, 315 U. S. 110, who bought and sold his milk intrastate though in competition with interstate milk, and the feeding of wheat on a farm by the appellee in *Wickard* v. *Filburn*, obviously were "local" transactions. *McDermott* v. *Wisconsin*, 228 U. S. 115, discussed, *infra*, pp. 39–42, and many cases under the National Labor Relations Act [14] indicate that there is nothing novel in subjecting transactions of retailers after commerce has ceased to the federal regulatory power, if such regulation is reasonably necessary to effectuate the objective of Congress in regulating interstate commerce.

As this Court stated in *United States* v. *Wrightwood Dairy*, 315 U. S., at 119, *Wickard* v. *Filburn*, 317 U. S., at 124, and *United States* v. *Darby*, 312 U. S. 100, 118–122:

> The commerce power is not confined in its exercise to the regulation of commerce among the states. It extends to those activities intrastate which so affect inter-

[14] *Labor Board* v. *Kudile*, 130 F. 2d 615 (C. C. A. 3), certiorari denied, 317 U. S. 694; *Labor Board* v. *J. L. Hudson Co.*, 135 F. 2d 380 (C. C. A. 6), certiorari denied, 320 U. S. 740; *J. L. Brandeis & Sons* v. *Labor Board*, 142 F. 2d 977 (C. C. A. 8), certiorari denied, 323 U. S. 751; *Labor Board* v. *M. E. Blatt Co.*, 143 F. 2d 268 (C. C. A. 3), certiorari denied, 323 U. S. 774; *Labor Board* v. *Suburban Lumber Co.*, 121 F. 2d 829 (C. C. A. 3), certiorari denied, 314 U. S. 693; *Loveman, Joseph & Loeb* v. *Labor Board*, 146 F. 2d 769 (C. C. A. 5); *Labor Board* v. *Richter's Bakery*, 140 F. 2d 870 (C. C. A. 5), certiorari denied, 322 U. S. 754.

> state commerce, or the exertion of the power of Congress over it, as to make regulation of them appropriate means to the attainment of a legitimate end, the effective execution of the granted power to regulate interstate commerce. * * * The power of Congress over interstate commerce is plenary and complete in itself, may be exercised to its utmost extent, and acknowledges no limitations other than are prescribed in the Constitution. * * *

And the *Wickard* and *Darby* cases also illustrate and hold that the commerce power may apply to individual intrastate acts which, in isolation, only have a trivial effect when the totality of similar transactions would have a substantial effect upon the regulation of commerce. See also *National Labor Relations Board* v. *Fainblatt*, 306 U. S. 601.

The Court has recently applied this test in upholding the application to intrastate transactions of the Food, Drug and Cosmetic Act itself; in *United States* v. *Walsh*, 331 U. S. 432, 437, the Court stated:

> The commerce clause of the Constitution is not to be interpreted so as to deny to Congress the power to make effective its regulation of interstate commerce.

We think that Section 301 (k) fully satisfies these tests. As we have shown, pp. 22–26, *supra*, in the Food, Drug, and Cosmetic Act Congress has

exercised its commerce power to control the labeling of products moving in interstate commerce in order to protect the ultimate consumer. No one questions that this statute and its objective are legitimate exertions of the federal power under the Commerce Clause. To provide that the labeling required for interstate shipment remain on the product until it is sold to the consumer is clearly an "appropriate means to the attainment of [this] legitimate end." For it is only by this means that there can be any assurance that the object of the regulation of the label in interstate commerce—consumer protection—will be achieved.

Under this statute a retailer who wishes to sell goods which come through the channels of interstate commerce must take them subject to the conditions as to accurate branding that Congress has imposed. He is not under compulsion to sell products which come from other states. If he chooses to do so, he must accept both the benefits of the Federal regulation which guarantees the accuracy of the branding of the goods which he receives and the obligation not to misbrand the products so received until they reach the consumer whom the regulation is designed to protect.

Furthermore, the court below did not doubt the power of Congress to reach articles held for sale by a retailer who receives them directly from an extrastate supplier, or to prevent destruction of the interstate label by any retailer holding the

articles for sale. This exercise of the commerce power would be readily subject to evasion, as we have seen, if retailers could avoid having to comply with the statute by arranging to purchase through an intrastate intermediary, or by transferring the article to another container instead of destroying the original label. Congress may provide for the "effective execution" of the granted power by closing these avenues of escape.

In the recent Committee report recommending a clarifying amendment to Section 301 (k) to overcome the decision below in the instant case (see pp. 19–20, *supra*), the House Committee on Interstate and Foreign Commerce stated (H. Rep. 807, 80th Cong., 1st sess., pp. 5–6):

> The Federal Food, Drug, and Cosmetic Act was passed to protect the health and pocketbook of the consuming public. Carefully drawn definitions of a wide variety of adulterations, misbrandings, and other offenses with respect to foods, drugs, devices, and cosmetics are set up by the act, and the channels of commerce are forbidden to the offending articles. In order to prevent the frustration and defeat of its purpose, Congress must exercise its power to continue that protection against articles that become filthy, decomposed, deteriorated, or otherwise adulterated or misbranded while awaiting sale to the ultimate consumer. Otherwise the safeguards which were designed to maintain the integrity of the products to the end of their interstate jour-

> ney become futile and the purpose of the regulation becomes sterile and fails of fruition.

These principles were applied by the Court under the original Food and Drugs Act almost thirty-five years ago in *McDermott v. Wisconsin*, 228 U. S. 115. We submit that Section 301 (k) is a statutory embodiment of that decision.

McDermott, a retail grocer in Wisconsin, purchased canned corn syrup in Illinois, the cans being shipped in wooden boxes. The labels on the cans conformed to the requirements of the Federal Food and Drugs Act. McDermott unpacked the containers in which the articles were shipped and placed the individual cans on his shelves for sale at retail. He left on the cans the labels which were on them during the course of their interstate journey. A Wisconsin statute would have required McDermott to remove the labels then on the cans and to place on them new labels which described the contents of the cans in different terms. McDermott was convicted in the State courts for failing to comply with the State law, and he brought the case to this Court, contending "that the Federal Food and Drugs Act passed under the authority of the Constitution has taken possession of this field of regulation and that the state act is a wrongful interference with the exclusive power of Congress over interstate commerce * * *." 228 U. S., at 127.

This Court reversed the conviction, and held the relevant provisions of the State law invalid

because they interfered with the operation of the Federal statute. The opinion of the Court stated (228 U. S. at 128):

> The Food and Drugs Act was passed by Congress, under its authority to exclude from interstate commerce impure and adulterated food and drugs and to prevent the facilities of such commerce being used to enable such articles to be transported throughout the country from their place of manufacture *to the people who consume and use them,* and it is in the light of the purpose and of the power exerted in its passage by Congress that this act must be considered and construed. *Hipolite Egg Co.* v. *United States* [220 U. S. 45].

The opinion pointed out, in the passage quoted at pages 24–25, *supra,* that to limit the protection under the statute to the box in which the goods were shipped in commerce, as distinct from the package to be purchased "by the consumer * * * would render the act nugatory and its provisions wholly inadequate to accomplish the purposes for which it was passed" (228 U. S. at 130–131). The Court held that the statute must be construed to require the correct brand on the package intended to reach the purchaser, and that, so construed, the requirements of the act were "clearly within the powers of Congress over the facilities of interstate commerce" (228 U. S. at 131). In answer to the argument that the commerce power extended only to the original package in which the goods were shipped inter-

state, the Court also stressed the importance, from the standpoint of enforcement of the regulation of the label carried in interstate commerce, of retaining the original label on the goods until they were sold (228 U. S., at 136).

Section 301 (k) specifically added to the present Act what this Court read into the misbranding provisions of the predecessor statute in the *McDermott* case. And the rationale of the *McDermott* decision in large measure demonstrates the constitutional basis for the provision. The *McDermott* decision recognized both that protection of the interstate label while the product is held for sale by the local dealer is an important enforcement device, and that to accomplish the statutory objective of protecting the consumer, Congress must have the power to control the labeling until the article reaches the ultimate purchaser for whom the label is intended.

The *McDermott* case, it is true, involved a retailer who purchased the products directly from outside the state. But nothing in the opinion or its reasoning turns on that fact, or suggests that the result would have differed if the goods had been received from an intermediary who had brought them into the state. When the goods were placed on the retailer's shelf for general sale, they were no longer in interstate commerce irrespective of whether they were purchased directly from outside the state or not. Cf. *Walling* v. *Jacksonville Paper Co.*, 317 U. S. 564.

There was thus the same need of showing a relationship between an intrastate transaction and the effective regulation of interstate commerce.

The court below sought to distinguish the *McDermott* case on the ground that although Congress may forbid the retailer to alter or destroy the interstate label and thus misbrand the article, it perhaps may not reach a situation in which the original physical label is not affected. But the difference between denying the retailer the right to destroy the label and denying him the right to accomplish the same thing by removing the article from its properly labeled container and placing it in a misbranded one is certainly not of constitutional stature. Either method of changing the label accomplishes the same result—frustration of the congressional objective to protect the consumer from misbranding. Congress certainly must possess the power to prohibit the one as much as the other.

The act here involved is not the only statute in which Congress has required that the labels prescribed for interstate or foreign commerce must remain on the goods until the ultimate sale. Thus Section 5 of the Wool Products Labeling Act of 1940 (54 Stat. 1128, 15 U. S. C. 68 c) requires any person manufacturing or first introducing into commerce a wool product to affix to it a label describing the content of the product, and

further provides that the label shall remain affixed to the product "until sold to the consumer."[15] Criminal penalties are provided for any person who with intent to violate the act alters or removes such a label (Secs. 5, 10, 15 U. S. C. 68c and 68h).

Section 6 of the Federal Caustic Poison Act of 1927 (44 Stat. 1406, 15 U. S. C. 406) prohibits the alteration, mutilation, etc., of any label on such a substance which is being "Shipped in interstate * * * commerce" or "Held for sale or exchange after having been so shipped." Section 5 (e) of the Federal Alcohol Administration Act of 1935 (49 Stat. 983, 27 U. S. C. 205 (e)) makes it unlawful to alter, destroy or remove any brand or label "upon distilled spirits * * * held for sale in interstate or foreign commerce or *after shipment therein*" except as authorized by federal law or administrative regulation. Section 6 (b) of the Importation of Adulterated Seeds Act, as amended by the Act of April 6, 1926, 44 Stat. 325, 326, provided, *inter alia,* for the condemnation of any misbranded seed which was "Held for sale or

[15] The Act provides for the use of substitute labels whenever a person subject to the act finds that the label affixed to the article does not comply with the act (Sec. 4 (c), 15 U. S. C. 68 b (c)), and it contemplates that where the wool product does not remain in the original state in which it is first labeled, as, for example, when wool material is made into a suit, that a substitute label shall be placed on the finished product (Sec. 5, 15 U. S. C. 68 c).

exchange after having been" transported in interstate commerce.[16] Section 304 of the Tariff Act of 1930 (19 U. S. C. 1304) requires that every article imported into the United States and its container and package be conspicuously marked or labeled in English to indicate the country of origin, and makes it an offense to remove or deface any such mark with intent to conceal the information given by it. See also, Meat Inspection Act of 1907, 34 Stat. 1263 (21 U. S. C. 79).

Except for a single case arising under the section of the Tariff Act just referred to, there has never even been a challenge to the provisions in these statutes extending congressional protection of the interstate label to the ultimate consumer.[17] That case, however, is very closely in point.

In *United States* v. *Ury*, 106 F. 2d 28 (C. C. A. 2), the defendant appears to have been a local retailer in automobile parts who removed the word "Germany" from a number of generators which had been imported from that country. The court construed Section 304 as "including a de-

[16] The provision has been superseded by section 404 of the Federal Seed Act, 53 Stat. 1286 (7 U. S. C. 1594) which, similarly to section 304 of the Tariff Act, provides that "No person shall detach, alter, deface, or destroy any label * * *, or alter or substitute seed in any manner" that would defeat the purpose of the Act.

[17] Another decision applying the tariff provision to the acts of retailers is *Didia* v. *United States*, 106 F. 2d 918 (C. C. A. 9).

facing or removal after the goods have come to rest in a state," and as "certainly" proscribing the removal of the mark or label while the article was held on the retailer's shelf for sale. The court rejected the argument that the provision so construed was unconstitutional, for reasons which are equally applicable here, saying (106 F. 2d, at 29):

> It is said that the provision goes too far, that it represents an effort to regulate the goods after they have ceased to be subject to federal control. If the provision stood alone, there would be force in the argument. But this enactment is not the equivalent of a statute requiring local retailers to place a mark of origin on all imported goods, goods previously unmarked. It merely commands that a mark already on them by force of a valid federal enactment shall not be disturbed. The provision is one reasonably calculated to render effective the principal requirement that the goods bear a mark at the time of importation. If the marks required on imported goods might later be defaced with impunity, the marking requirement would be evaded and the fair operation of the law defeated. Congress, having exercised its undoubted power to require marks at importation, had also the incidental power to forbid the defacing of the mark at any time after importation. * * *

It thus appears that the method adopted in the Food, Drug and Cosmetic Act for insuring that the correct interstate labeling reaches the ultimate consumer is neither novel nor unique. It has been embodied in other statutes whose validity either has been assumed or upheld. We submit that this Court should be reluctant to overturn the repeated congressional judgment that protecting the interstate label until it reaches the ultimate consumer for whom alone it is meant is a proper exercise of the commerce power.

This Court has frequently recognized that Congress possesses the "choice of means" for the accomplishment of the powers granted to it (*McCulloch* v. *Maryland*, 4 Wheat. 316, 409–421; *United States* v. *Fisher*, 2 Cranch 358, 396; *Legal Tender Case*, 110 U. S. 420, 440; *Everard's Breweries* v. *Day*, 265 U. S. 545, 560; *First National Bank* v. *Union Trust Co.*, 244 U. S. 416, 419). The principle has often been applied in cases involving the regulation of intrastate transactions under the Commerce Clause. *Stafford* v. *Wallace*, 258 U. S. 495, 521; *Chicago Board of Trade* v. *Olsen*, 262 U. S. 1, 37; *United States* v. *Darby*, 312 U. S. 100, 121–122; *Virginian Ry. Co.* v. *System Federation*, 300 U. S. 515, 553; *Wickard* v. *Filburn*, 317 U. S. 111, 128–129. Cf. *United States* v. *Carolene Products Co.*, 304 U. S. 144, 152. Congress has shown quite plainly in respect of the present statute, as well as in the similar provisions to which we have referred, that it

regards protection of the interstate label as a necessary means for accomplishing its purpose.

It is no answer to suggest, as the court below does (R. 61), that the laws of the state in which respondent does business are adequate to complement the federal food and drug legislation and thus to protect the consumer from the evils at which the federal legislation is directed. It is for Congress to determine the national policy over interstate commerce, irrespective of state law, and the congressional enactment is no less valid because some of the states may have acted to meet the same evil. Cf. *United States* v. *Darby*, 312 U. S. at 114. Furthermore, only about 13 of the 48 states have laws which approach the scope of the Federal Food, Drug, and Cosmetic Act.[18]

[18] These are:

California.—Cal. Health and Safety Code (Deering, 1945), Div. 21, chapters 2 and 3; as to dangerous cosmetics, see Penal Code (Deering, 1941), sec. 382.6.

Connecticut.—Connecticut Food, Drug and Cosmetic Act, Conn. Gen. Stat. (Supp. 1939), sec. 886e, et seq., as amended.

Florida.—Florida Food, Drug and Cosmetic Law, Fla. Stat. (1941), sec. 500.01 et seq., as amended.

Indiana.—Uniform Indiana Food, Drug, and Cosmetic Act, c. 38, Acts of 1939, as amended.

Louisiana.—State Food, Drugs, and Cosmetic Act, Act No. 142, Acts of 1936, as amended.

Missouri.—Act of Aug. 5, 1943 entitled Food and Drugs, secs. 1, 9857–9878A.

Nevada.—Nevada Food, Drug and Cosmetic Act, Nev. Comp. Laws (Supp. 1941), secs. 6206–6206.20.

New Jersey.—N. J. Rev. Stat. (1937), secs. 24:1–1 to 24:6–8, incl., as amended by c. 320, Laws of 1939.

New York.—Baldwin's Consolidated Laws of New York,

Without attempting any detailed discussion of the structure and enforcement of the food and drug laws in the individual states, it is unlikely that any of the individual states has or can expect to have the wide variety of skilled professional personnel whose special talents must be available to deal with the varied problems that arise. Nor can the states be expected to install, equip, and maintain the expensive laboratory facilities necessary to deal with the technical matters involved. It would be an impractical duplication of effort for them to do so, for most drugs in use at the present time are distributed on a multi-state scale. Moreover, variant state requirements would seriously burden the interstate distributor.

It is to be noted that the House Committee Report concerned with overcoming the decision below in the instant case took special cognizance of the effect of the proposed amendments upon federal-state relationships. The report observed not only that the amendments would not disturb

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Agriculture and Markets Law, Article 17, and Education Law, Article 51, as amended.

North Carolina.—North Carolina Food, Drug and Cosmetic Act, N. C. Gen. Stat. (Mickie, et al., 1943), secs. 106–120 to 106–145, incl.

Tennessee.—Tennessee Food, Drug and Cosmetic Act, c. 120, Public Acts, 1941.

Virginia.—Va. Code (Mickie, et al., 1942), secs. 1190 (a)–1190 (p), 1655–1664e, 1698a–1698e.

Washington.—Uniform Washington Food, Drug, and Cosmetic Act, c. 257, Session Laws, 1945.

the preexisting cooperative relationship, but that the proposed amendment already had been approved by the association of state and city food and drug enforcement officers. This portion of the report, which includes the resolution of the local enforcement officers is set forth in the note below.[19]

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[19] H. Rep. No. 807, 80th Cong., 1st Sess., pp. 6–7.

"The enactment of the proposed amendments would not have the effect of excluding State authority in the same field (*Savage* v. *Jones*, 225 U. S. 501). The Food and Drug Administration has worked cooperatively with the States, and the amendments are not intended to disturb that relationship. The needs for consumer protection are such as to require at least the combined efforts of Federal and local authorities.

"Approval of these proposed amendments is expressed in the following resolution adopted unanimously on June 20, 1947, by the Association of Food and Drug Officials, primarily made up of State and city enforcement officers, in its annual conference attended by representatives of 32 State-enforcement organizations:

'RESOLUTION

'In the matter of H. R. 3128 and 3147 and S. 1190 now pending before the Congress. Whereas recent decisions by the Federal courts have seriously restricted the applicability of the Federal Food, Drug, and Cosmetic Act, to interstate shipments of foods, drugs, cosmetics, and therapeutic devices that become adulterated or misbranded after the completion of their interstate transportation, thus drastically curtailing the public protection heretofore afforded under the Federal act; and

'Whereas the States and local authorities have, by common understanding, come to rely in great measure upon the Food and Drug Administration for the inspection and supervision of interstate shipments of foods, drugs, cosmetics, and

The House Committee on Interstate and Foreign Commerce, which has charge of food and drug regulation, has advanced another reason why protection of the product until it reaches the consumer is a proper means of safeguarding interstate commerce. In reporting the proposed

devices to insure that, from these sources, only products that are free from adulteration and misbranding, are delivered to consumers, thus permitting the assignment of the inspectional staffs of State and local agencies to problems more particularly concerned with the commerce of the States; and

'Whereas the activities of the Food and Drug Administration in connection with such goods have been very effective against products which have become contaminated with filth, or otherwise adulterated or misbranded at destination; and

'Whereas the Food and Drug Administration has successfully maintained a program of surveillance over commodities falling within this category without friction or conflict with State law-enforcement agencies exercising like functions with respect to products in the commerce of the State; and

'Whereas the funds and facilities of State and local agencies are generally inadequate to afford satisfactory consumer protection from abuses which occur in this field unless their efforts can be supplemented by enforcement activities under the Federal act; and

'Whereas it has long been the policy and practice of the various State and local agencies and the Food and Drug Administration to plan their respective programs so that the regulatory activities of each will harmonize with and supplement the operations of the other, through the pooling of resources for concerted action where conditions require, or the planning for careful division of work so that personnel can be deployed for maximum coverage to give the consuming public and responsible industry the greatest degree of protection possible within their respective and concurrent jurisdictions: Be it therefore

'*Resolved*, That the Association of Food and Drug Officials of the United States in annual conference assembled in

clarifying amendments to Section 301 (k) (see H. Rep. No. 807, 80th Cong., 1st sess., pp. 19–20, *supra*), the Committee described the effect of sales of misbranded or adulterated products upon the public confidence in the products themselves, and consequently upon the volume of commerce in such products, stating (pp. 4–5):

> It is well known that the defilement of products or deterioration in quality or misrepresentation through relabeling or other abusive acts which occur at any time before articles have been sold to consumers lead to dissatisfaction and lack of confidence

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Carlsbad, N. Mex., express its firm belief in the soundness of the proposal to amend section 304 of the Federal Food, Drug, and Cosmetic Act so as to extend the jurisdiction of the act to products shipped interstate which may become adulterated or misbranded after the interstate transportation has been completed; and that such jurisdiction be extended to the limit of the constitutional authority of the Congress so as to include not only the first sale but subsequent sales as a means of consumer protection and to prevent undue burdens on legitimate interstate commerce; and be it further

'*Resolved*, That it is the belief of this association that the provisions of section 301 (k) should be extended to prohibit acts which result in adulteration as well as misbranding and should be so framed as to be coextensive in all respects with the amended seizure provisions of the Food, Drug, and Cosmetic Act as above proposed; be it further

'*Resolved*, That a copy of this resolution be forwarded by air mail to Hon. Charles A. Wolverton, chairman, Committee on Interstate and Foreign Commerce, House of Representatives; to Hon. Robert Hale, chairman, subcommittee of the House, and to Hon. Wallace H. White, Jr., chairman, Committee on Interstate and Foreign Commerce, United States Senate.'"

which depresses the interstate demand for goods of the same type that are neither adulterated nor misbranded. Testimony before the committee repeatedly referred to that fact. Such abusive acts necessarily and inevitably affect the ability of out-of-State manufacturers to continue marketing their products. If the volume of interstate commerce in foods, drugs, devices, or cosmetics is to be maintained and extended it is necessary that the integrity of the products be preserved, so far as possible, up to the time of purchase by the ultimate consumer. The reputation of any nationally distributed product is impaired and the interstate commerce therein is depressed by adulteration or misbranding while the article is awaiting sale. This is especially true where such adulteration presents a threat to the public health. The misbranding or adulteration of drugs while they are being held for sale which renders their use unsafe or unsuitable because of failure to bear adequate directions for use or warnings against probable misuse, or for any other reason, tends to bring those articles into disrepute and to restrict their proper use. Misbranding which results in ineffectual treatment with a potent drug, such as those of the sulfonamide group, may render the disease organisms immune to the drug. When that resistant strain is spread in the community the sulfonamides are ineffective, even when used by skilled physicians, with the consequence that the

interstate market for those useful drugs is substantially depressed.

Most foods, drugs, devices, and cosmetics are distributed on a multi-State scale. In order to use the facilities of interstate commerce, those articles must be in compliance with the act. Most merchants must obtain any such article, either directly or indirectly, from an out-of-State source or be without it. Public confidence in the effectiveness of interstate regulation inures to the benefit of local distributors through the resulting increase in consumer demand. Having accepted the advantages flowing from interstate regulation, local distributors should not be left free to do acts which deny to consumers the protection Congress intends they should have, and which, in practical effect, appropriate the channels of interstate commerce as an instrumentality for working harm upon consumers.

We submit that the facts set forth in this passage from the Committee Report afford an additional reason for holding that the Congress may legitimately exercise its commerce power so as to require correct labeling up to the point of sale to the ultimate consumer.

The view which we urge does not impose hardship on the local retailer. Specifically, with respect to respondent, the container of sulfathiazole which he purchased from the jobber had a proper interstate label, and this label, in addition to bearing a warning concerning "severe toxic reac-

tions" which the drug might cause, plainly informed respondent: "Caution—to be used only by or on the prescription of a physician." See *supra*, p. 8. Respondent need only have heeded the cautionary instructions and dispensed the medicine pursuant to a physician's prescription; he would have had adequate directions for use as prescribed by the physician and these would have been reflected on the prescription label which is placed on such products. It is solely because respondent flaunted the warning and cautionary instructions placed on the product by the producer for the benefit of the consumer that he finds himself in his present predicament.

It is true that if a distributor or dealer undertakes to sell the interstate article in smaller quantities than the original package the smaller packages, too, must be properly labeled. But this is not a great burden. In most instances the manufacturer not only labels the interstate container, but also the individual packages placed therein, as is the case of canned goods. In these circumstances the local seller is required only to leave the label alone. Where this is not the situation, the choice is between placing the responsibility on the retailer to affix appropriate labels on the packages which he holds for sale, as under the Wool Products Labeling Act where the wool has been manufactured into clothing (see *supra*, p. 43), or to defeat the congressional purpose by

permitting the retailer to separate the articles from their interstate label and to hold them for sale either without labeling or with improper labeling. The danger to purchasers of improperly labeled drugs clearly outweighs any inconvenience to the seller from having to copy the label.

CONCLUSION

For the reasons stated we respectfully submit that the judgment of the circuit court of appeals should be reversed.

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NOVEMBER 1947.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1946.

No. 1473

UNITED STATES OF AMERICA,

Petitioner,

versus

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY,

Respondent.

BRIEF OF RESPONDENT IN OPPOSITION TO THE GRANT OF THE WRIT OF CERTIORARI.

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CITATIONS.

IN THE

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JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY,

Respondent.

BRIEF OF RESPONDENT IN OPPOSITION TO THE GRANT OF THE WRIT OF CERTIORARI.

Respondent, Jordan James Sullivan, respectfully submits that the Circuit Court of Appeals did not err in reversing the judgment of the District Court, and that the grant of the writ in this case should be denied for the following reasons:

I.

IT IS NOT THE PURPOSE OR INTENT OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT TO REGULATE THE INTRASTATE, OVER-THE-COUNTER RETAIL SALES OF FOODS, DRUGS, COSMETICS AND DEVICES, OR TO PRESCRIBE HOW AND IN WHAT MANNER SUCH ARTICLES, WHEN SO SOLD, SHOULD BE LABELED OR BRANDED.

The purpose of the Act, as plainly and clearly expressed in its title, is to prohibit the movement in interstate com-

merce of adulterated and misbranded foods, drugs, cosmetics and devices. The Act is in aid of, and not a usurpation of, the police powers of the several states, to the end that the public health and safety might be advanced. The Act indicates its intent to respect the recognized line of distinction between domestic and interstate commerce. It does not interfere with state regulations of selling at retail. The construction urged by the government would give a federal agency control over myriads of local businesses in matters heretofore traditionally left to local law, and would really be a direct regulation for police purposes of what is plainly intrastate commerce, which is peculiarly the province of the state. Such a construction would be an inroad upon local conditions and standards of such far-reaching import as would destroy the distinction which the commerce clause itself established between commerce among the several states and the internal concerns of a state.

Weigle vs. Curtice, 248 U. S. 285.
Federal Trade Commission vs. Bunte Bros., 312 U. S. 342.
National Labor Relations Board vs. Jones, 301 U. S. 1.
U. S. vs. Walsh, 67 S. C. T. 1283.

But it is said that to deny the Food and Drug Administration the right to regulate purely intrastate retail sales would seriously impair the functioning of the administration, and would defeat the purpose of the Act. This certainly is not true if the purpose of the Act is to keep interstate channels free of adulterated and misbranded articles, and the administration will confine its function-

ing to such purposes. To say that the public health will not be protected if the administration does not have power to regulate retail sales is to say that the several states will not, or cannot, enforce their laws, for such laws are unquestionably adequate. But the administration wants a completely centralized control, and not a dual system as created by our Constitution and as has existed until now. The administration's function is to keep adulterated and misbranded articles out of interstate commerce so that the state regulation of local retail selling will be more effective in protecting the health and safety of its citizens.

II.

SECTION 301K, AND PARTICULARLY THAT PART OF SAID SECTION READING: "OR THE DOING OF ANY OTHER ACT WITH RESPECT TO A FOOD, DRUG . . . IF SUCH ACT IS DONE WHILE SUCH ARTICLE IS HELD FOR SALE AFTER SHIPMENT IN INTERSTATE COMMERCE AND RESULTS IN SUCH ARTICLE BEING MISBRANDED", IS TOO VAGUE, UNCERTAIN AND INDEFINITE AS APPLIED TO ACTS OF RESPONDENT TO BE ENFORCEABLE AS A CRIMINAL STATUTE.

A criminal statute should be definite and certain. It should define its orbit with exactitude so that a citizen may be aware of the penalties attendant upon a certain course of conduct. The dividing line between unlawful and lawful acts should not be left to conjecture; there should be no constructive offenses. Liberty is a precious attribute; fine and imprisonment are harsh deterrents. The prohibitive acts should be so clearly expressed and de-

fined that the ordinary person can know in advance how to avoid an unlawful course of conduct and so that only the foolhardy or vicious will be penalized. Respondent insists that no ordinary grocer, druggist, barber, beautician or other retail dealer in foods, drugs, cosmetics and devices would understand from the language of Section 301K that unless he labeled an article sold over-the-counter in the manner prescribed by the Act that he would be guilty of a crime punishable by fine and imprisonment.

Krause vs. U. S., 327 U. S. 614.
U. S. vs. Resnich, 299 U. S. 207.
Fasulo vs. U. S., 272 U. S. 620.
U. S. vs. Weitzel, 246 U. S. 533 (at page 543).
U. S. vs. Harris, 177 U. S. 305.
U. S. vs. Wiltberger, 5 Wheaton 76.

III.

IF THE ACT IS CONSTRUED AS APPLIED TO RESPONDENT'S INTRASTATE ACTS, THEN SAID ACT IS INVALID AND UNCONSTITUTIONAL IN THAT IT IS IN VIOLATION OF THE TENTH AMENDMENT TO THE CONSTITUTION OF THE UNITED STATES, AND IS AN INVASION OF THE RESERVED POLICE POWERS OF THE STATE.

The Respondent's acts were purely intrastate, and after the interstate commerce had ended. No conspiracy or fraudulent intent was alleged or shown. Such retail sales could no more have affected interstate commerce than the retail sale of like articles domestically produced. Such sales did not and could not directly or substantially, bur-

den or obstruct interstate commerce or in any wise prevent the government from keeping out of the channels of interstate commerce, adulterated or misbranded articles. Congress does not have the power to regulate intrastate commerce, irrespective of its effect upon interstate commerce. This Act, if construed as the government contends, is clearly unconstitutional and invalid.

Shechter Poultry Corp. vs. U. S., 295 U. S. 495.

To adopt the construction of the Act urged by the administration in this case would be to destroy the power of the state to regulate the retail sale of foods and drugs, and to deny the right of the state to protect the health and safety of its citizens under the police powers reserved to it under the Constitution.

Respondent submits that the decision of the Circuit Court is not erroneous for any of the reasons assigned, and that the writ of certiorari should be denied.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1947.

No. 121

UNITED STATES OF AMERICA,

Petitioner,

versus

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY,

Respondent.

On Writ of Certiorari to the Circuit Court of Appeals for the Fifth Circuit.

BRIEF FOR THE RESPONDENT.

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JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY,
Respondent.

On Writ of Certiorari to the Circuit Court of Appeals for the Fifth Circuit.

BRIEF FOR THE RESPONDENT.

STATEMENT OF THE CASE.

The respondent Sullivan, a local retail merchant in Columbus, Georgia, in the month of December, 1944, made two (2) over-the-counter retail sales, in his drug store, of twelve (12) sulfathiazole tablets each, which were

not labeled as provided by the Federal Food, Drug and Cosmetic Act. He was convicted in the District Court for having violated Sec. 301 (k) of the Act (67 Fed. Supp. 192) and the Court of Appeals reversed this judgment with direction to acquit (161 F. 2nd 629).

The two (2) over-the-counter retail sales were made to different federal food and drug inspectors. One of the retail sales involved was made on December 13, 1944 (R. 4), and the other on December 14, 1944 (R. 6). Immediately preceding each retail sale the tablets were removed from a bottle on the shelf of respondent's drug store, and placed in a pill box labeled only "Sulfathiazole". At the time of said sales the bottle from which the tablets were removed was labeled in accordance with the Act. This bottle, so labeled, originally contained one thousand (1,000) tablets, at least nine (9) months before said sales, at some time between November 23, 1943 and March 15, 1944, had been shipped in interstate commerce from North Chicago, Illinois, to Abbott Laboratories in Atlanta, Georgia, and thereafter, on or about September 29, 1944, had been sold and delivered by Abbott in Atlanta, Georgia, to the respondent. This bottle was taken in charge by the inspectors after said retail sales, and its labeling up to the time of said retail sales had not been altered, mutilated, obliterated, destroyed or removed. It will be noted that the bottle remained with the importer in Atlanta, Georgia, at least a little over six (6) months before it was sold and shipped intrastate to the retailer at Columbus, Georgia; that it was kept on the shelf of the retailer in his drug store over two (2) months

before the sales were made; and, that at least nine (9) months elapsed after the interstate commerce was completed in Atlanta, Georgia, before the retail sales were made in Columbus, Georgia.

The information charged that respondent, by reason of the removal of said tablets from said bottle and the sale and delivery of them in a pill box, labeled as aforesaid, had violated Sec. 301 (k) of the Act, in that the labeling on the pill box did not contain adequate directions for use or adequate warning against use as provided in Sec. 502 (f) (1) and (2) of the Act.

The respondent made a motion to dismiss the information on the grounds that no offense was alleged; that respondent's acts were in intrastate commerce and were beyond the power of Congress to regulate, control or punish; that properly construed, the Act only applies to misbranding in interstate commerce, and if construed as applying to the acts of respondent, is unconstitutional. The trial court overruled respondent's motion to dismiss, and after the conclusion of the evidence upon the trial, which was before the Court without a jury, respondent made a motion for a judgment of acquittal upon the evidence (R. 47), which motion was overruled by the Court. Thereupon the Court entered a judgment of conviction, and then respondent filed his appeal.

QUESTIONS PRESENTED.

1. Is it the purpose and intention of the Federal Food, Drug and Cosmetic Act to regulate the intrastate retail sale of food and drugs and to regulate the labeling of foods and drugs when sold at retail in intrastate commerce?

2. Is Sec. 301 (k) of the Act, as applied to the acts of respondent, too vague, indefinite and uncertain to be enforceable?

3. If the Act, properly construed, applies to the acts of respondent, is it unconstitutional and in violation of the Tenth Amendment to the Constitution of the United States?

SUMMARY OF ARGUMENT.

1. The general purpose of the Act is declared in its title: "An Act to prohibit the movement in interstate commerce of adulterated and misbranded foods, drugs, devices and cosmetics, and for other purposes." The Act does not intend to interfere with State regulation of selling at retail. The Act intends to respect the recognized line of distinction betdeen domestic and interstate commerce. It naturally would, as the distinction is constitutional. The Act seeks to keep interstate channels free of adulterated and misbranded articles to the end that the public health and safety might be advanced. It seeks to aid the States in making more effective their health

regulations, enacted in the exercise of the police power reserved to the States, so that the health and welfare of the citizens of the various States may be protected. There is no indication of any intention to regulate intrastate commerce because of any burdensome affect on interstate commerce. The talismanic expression "affecting interstate commerce" is not used. There are no findings or recitals in the Act that regulation of intrastate acts is necessary to effectuate the purpose of the Act. Nothing is more local than a retail sale. The Court should await a clearer mandate from Congress before adopting a construction of the statute which would be an inroad upon local conditions and local standards of such far-reaching import. The Court should so construe an act as to even avoid a serious doubt as to its constitutionality. The Court should not construe the act so as to give a federal agency control over myriads of local businesses heretofore traditionally left to local law, and make criminals of thousands of local grocers and druggists who sell intrastate from imported packages without mutilating the label.

2. Sec. 301 (k), and particularly that part of said section reading, "or the doing of any other act with respect to a food, drug, device or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded," as applied to the acts of respondent, is too vague, indefinite and uncertain to be enforceable as a criminal statute. A criminal statute should be strictly construed no matter what is its beneficient purpose. The

criminal action must be so explicitly and unambiguously defined that the ordinary man can know in advance how to avoid a criminal course of action. The prohibited acts should be defined with such care that only the foolhardy or vicious will be penalized. It is not permissible for the Court to search for an intention that the words themselves do not suggest. Sec. 301 (k) does not say that a person who buys in bulk any food or drug cannot sell in intrastate commerce at retail any part of such food or drug unless that part of such food or drug is labeled in accordance with the provisions of the Act, and that if such intrastate seller does not so label such food or drug that he will be guilty of a crime and be subject to a fine and imprisonment. In this case the interstate label was not changed or tampered with. The attempt here made is to extend Sec. 301 (k) so as to make criminal all retail sales made from the interstate package, though made clearly in intrastate commerce unless the labeling required by the Act is placed on the retail package. We insist that no grocer or druggist thus breaking an interstate package for a retail sale has understood that this was necessary. The Act has been in force since 1938, and yet we have been unable to find, and the government has not cited, a single reported case where the Food and Drug Administration has sought to prosecute a retail seller under the facts here involved.

3. If the Act is construed as applying to the acts of respondent, then the Act is unconstitutional and in violation of the Tenth Amendment to the Constitution of the United States, for it is a direct regulation for police

purposes of what is plainly intrastate commerce, which is the peculiar province of the State.

The authority of Congress and the scope of its power to regulate intrastate acts must be considered in the light of our dual system of government, and may not be extended so far as to embrace effects upon interstate commerce so indirect and remote, that to embrace them would effectually obliterate the distinction between what is national and what is local and create a completely centralized government. Such power cannot destroy the distinction which the commerce clause itself established between commerce among the several states and the internal concerns of a State. Congress has no power to substitute its will for that of the State in local matters, even though it may believe that the State, in its exercise of the police powers reserved to it, is unable or unwilling to enact and enforce legislation for the protection and advancement of the health of its citizens. The retail sales here involved did not and could not directly or substantially affect interstate commerce, and did not prevent Congress from prohibiting the movement in interstate commerce of adulterated and misbranded foods and drugs, which the statute states is its purpose. Therefore the Act is unconstitutional and void if properly construed as applying to the retail sales made by respondent.

ARGUMENT.

1. The Federal Food, Drug and Cosmetic Act does not and is not intended to apply to retail sales in intrastate commerce, or to misbranding in intrastate commerce. Stretch the Act as you will, its purpose is stated in its caption to be: "To prohibit the movement in *interstate commerce** of adulterated and misbranded foods, drugs, devices and cosmetics, and for other purposes." The statute rests, of course, upon the power of Congress to regulate interstate commerce, just as did the 1906 Food and Drug Act. As stated by Mr. Justice Holmes in *Weigle vs. Curtice, 248 U. S. 285,* at page 288:

> "The Food and Drugs Act indicates its intention to respect the recognized line of distinction between domestic and interstate commerce too clearly to need argument or an examination of its language. It naturally would, as the distinction is constitutional . . . When objects of commerce get within the sphere of State legislation, the State may exercise its independent judgment . . . When they get within that sphere is determined by the old long-established criteria. The Food and Drugs Act does not interfere with State regulation of selling at retail."

In *Nigro vs. United States 276 U. S. 332,* where the defendant was prosecuted for violating the Anti-Narcotic Act in that he sold morphine not in pursuance of a written order of the buyer on a form issued in blank for that purpose by the Commissioner of Revenue, the Court said:

> "If it is a mere act for the purpose of regulating and restraining the purchase of the opiate and other

* The italics in this brief are added.

drugs, it is beyond the power of Congress and invalid. We must assume it is a taxing measure for otherwise it would be no law at all."

In *FTC vs. Bunte Brothers, 312 U. S. 349*, where the commission issued a cease and desist order against Bunte for selling break and take packages in intrastate commerce, which was alleged to be in violation of the Federal Trade Commission Act, the Supreme Court, speaking through Mr: Justice Frankfurter, said in part:

"The construction of Section 5 urged by the Commission would thus give a Federal agency control over myriads of local businesses in matters heretofore traditionally left to local custom or local law . . . An inroad upon local conditions and local standards of such far-reaching import as involved here ought to await a clearer mandate from Congress."

It will be noted that the Federal Food, Drug and Cosmetic Act, like the Federal Trade Commission Act, and unlike the National Labor Relations Act and many other acts of Congress, does not expressly undertake to regulate matters affecting interstate commerce. As said by the Court in the *Bunte* case:

"When in order to protect interstate commerce Congress has regulated activities, which, in isolation, are merely local, it has normally conveyed its purpose explicitly . . .

". . . to read 'unfair methods of competition in (interstate) commerce' as though it meant 'unfair methods of competition in any way affecting interstate commerce', requires, in view of all the relevant

considerations, much clearer manifestations of intention than Congress has furnished."

Again, as stated in *National Labor Relations Board vs. Jones, 301 U. S. 1:*

> "The authority of the Federal Government may not be pushed to such an extreme as to destroy the distinction which the commerce clause itself established between commerce among the several States and the internal concerns of a State . . . The cardinal principle of statutory construction is to save and not to destroy. We have repeatedly held that as between two possible constructions of a statute, by one of which it would be unconstitutional and by the other valid, our plain duty is to adopt that which will save the act. Even to avoid a serious doubt the rule is the same . . . The critical words of this statute prescribing the limits of the board's authority in dealing with labor practices are 'affecting commerce'. Undoubtedly the scope of this power must be considered in the light of our dual system of government and may not be extended so as to embrace effects upon interstate commerce so indirect and remote that to embrace them, in view of our complex society, would effectually obliterate the distinction between what is national and what is local and create a completely centralized government."

The Federal Food, Drug and Cosmetic Act, to the end that the public health and safety might be advanced, seeks to keep *interstate* channels free of adulterated and misbranded drugs.

U. S. vs. Walsh, 331 U. S. 432.

The Act is in aid of the several States in the exercise of their police power to protect the health of their citizens. It is not a usurpation of such power. There is no indication of any intention to regulate intrastate commerce because of any burdensome affect on interstate commerce. There are no findings or recitals in the Act that it is necessary to regulate intrastate retail sales in order to effectuate the purposes of the Act. There is no reported case that we have been able to find and none have been cited by the government where the Food and Drug Administration has sought to regulate retail sales in intrastate commerce. That the Act has been successfully administered since 1938 without attempting to regulate retail sales is a persuasive reason to believe that it is not necessary to regulate retail sales in order to effectuate the purposes of the Act.

The government contends that the purpose to regulate retail sales is expressed in Sec. 301 (k), and particularly in the words "or the doing of any other act with respect to a food, drug, device or cosmetic while such article is held for sale after shipment in interstate commerce," and further says that Sec. 301 (k) is a statutory embodiment of this Court's decision in *McDermott vs. Wisconsin, 228 U. S. 115.* In the *McDermott* case, at pages 132 and 133, it is said:

> "The label on the unsold article is, in the one case, the evidence of the shipper that he has complied with the Act of Congress, while in the other, by its misleading and false character, it furnishes the proof upon which the federal authorities depend to reach and punish *the shipper* and to condemn the goods.

If truly labeled within the meaning of the Act, his goods are immune from seizure by the federal government; if the label is false or misleading within the terms of the law, the goods may be seized and condemned. In other words, the label is the means of vindication, or the basis of punishment in determining the character of the interstate shipment dealt with by Congress. In this connection it might be noted that as a practical matter, at least, the first time the opportunity of inspection by the federal authorities arises in cases like the present is when the goods, after having been manufactured, put up in package form and boxes in one State, and having been transported in interstate commerce, arrive at their destination, are delivered to the consignee, unboxed, and placed by him upon the shelves of his store for sale."

And on page 134 of the same case, it is said:

"To require the removal or destruction before the goods are sold of the evidence which Congress has by the Food and Drug Act, as we shall see, provided may be examined to determine the compliance or noncompliance with the regulations of the Federal Law, is beyond the power of the State."

And, again, on pages 135 and 136, it is said:

"For, as we have said, keeping within the constitutional limitations of authority, Congress may determine for itself the character of the means necessary to make its purpose effectual in preventing the shipment in interstate commerce of articles of a harmful character, and to this end may provide the means of inspection, examination, and seizure necessary to enforce the prohibitions of the Act, and when Par. 2

> has been violated, the federal authority, in enforcing either Par. 2 or Par. 10, may follow the adulterated or misbranded article *at least to the shelf of the importer* . . . The opportunity for inspection en route may be very inadequate. The real opportunity of government inspection may only arise, when, as in the present case, the goods as packed have been removed from the outside box in which they were shipped and remain as the Act provides, 'unsold'."

If Sec. 301 (k) is an embodiment of the McDermott case, it means that no one—at least the importer—may destroy the evidence—that is, the label on the goods shipped interstate—for to do so would deprive the interstate shipper of his means of vindication that he had labeled the interstate shipment according to the Federal Law, or on the other hand, would deprive the government of the evidence necessary to punish the interstate shipper for having shipped misbranded goods in interstate commerce.

In Sec. Ten (10) of the Food and Drug Act of 1906 (21 U. S. Code, Sec. 14; Chap. 3915, Sec. 10, 34 Stat. 771-772) which was before the Court in the *McDermott* case, following language is used:

> "Any article of food, drug or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State . . . to another for sale, or having been transported, *remains unloaded, unsold, or in original unbroken* packages . . . shall be liable to be proceeded against . . . and seized for confiscation . . ."

In the above language the unsold article was subject to seizure if it was misbranded while in interstate commerce. The McDermott case only holds that Congress has the power to require the evidence—the interstate label—to be preserved. And Sec. 301 (k) only means that the evidence cannot be destroyed—that the label that was on the package shipped in interstate commerce cannot be altered, obliterated, removed or destroyed. This is an entirely different thing from saying that a retail dealer cannot break an interstate package and make retail sales in intrastate commerce therefrom without labeling the retail sales as provided by the Act. In the case at bar, respondent did not interfere with the interstate label on the bottle—such label remained intact on the bottle all the while the article was held for sale.

If it was the intention of Congress by this section of the Act to regulate retail sales and the branding of articles sold in intrastate commerce, why didn't the legislative draftsman say so in plain unmistakable language? If that was the intention of Congress, which we insist is not true, the words "or the doing of any other act with respect to a drug while said article is held for sale after shipment in interstate commerce," did not say so. In the quoted language the word "sale" is in the singular. The *McDermott* case says that the federal authority may follow the misbranded article to the shelf of the importer to obtain the evidence that misbranded goods have been shipped in interstate commerce. This language fairly implies that while the misbranded goods remained on the shelf of the importer the government had a fair and

sufficient opportunity to inspect and examine the interstate labels to see whether or not misbranded goods had been shipped in interstate commerce, and therefore, after the sale by the importer it was not necessary to require the preservation of the interstate label.

Respondent insists that Sec. 301 (k) does not apply to retail intrastate sales made from interstate bulk packages, regardless of whether the retailer is the importer of the interstate bulk package or not. However, the importer who alters the label of an interstate package violates Sec. 301 (k) whether he is a retailer or not; but, whether a retailer who is not the importer and who alters the interstate label violates Sec. 301 (k) is immaterial in this case, because respondent did nothing whatever to the label on the bottle that had been shipped in interstate commerce.

But the government says that unless the Act is construed as requiring all retail dealers to label their retail intrastate sales of food, drugs, cosmetics and devices in accordance with the provisions of the Act, the public health will not be protected. Why? Is it assumed that the several States are unable or unwilling to protect their people?

Respondent, therefore, respectfully submits that the Federal Food, Drug and Cosmetic Act, when properly construed, does not apply to the acts of respondent.

2. Sec. 301 (k) of the Act and particularly the following language, "or the doing of any other act with re-

spect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce, and results in such article being misbranded," as applied to the acts of respondent is too vague, indefinite and uncertain to be enforceable as a criminal statute, for it did not adequately inform respondent that if he made an over-the-counter retail sale in intrastate commerce of a drug, that at some time in the past had been shipped in interstate commerce, that then he would be a criminal if he did not label such retail sale as provided by the Act.

All that respondent did in this case was to make two (2) over-the-counter retail sales in intrastate commerce from a bulk container—a bottle that had previously been shipped in interstate commerce. These retail sales were not labeled as required by the Act. But the bulk container—the bottle—was so labeled from the time it was shipped in interstate commerce until after said retail sales were made. This bottle was purchased by respondent in intrastate commerce in Atlanta, Georgia, some six (6) to ten (10) months after it had been received in interstate commerce by Abbott Laboratories, the seller. Respondent did not destroy any evidence that the government might need to prove that the bottle was either properly or improperly branded when shipped in interstate commerce. Even if he had altered the label on the bottle, the government had had from six (6) to ten (10) months to examine and inspect the bottle in Atlanta, Georgia, after it had been received in interstate commerce and had been unpacked from the outside shipping container. If

the criminal provision applies here, it applies to all retail sales of drugs, foods, cosmetics and devices no matter how many intermediate intrastate sales have been made, and no matter how long after such foods, drugs, cosmetics and devices had been in interstate commerce, and no matter whether such foods, drugs, cosmetics and devices had been shipped in interstate commerce in bulk or in retail containers.

It is one of the most fundamental precepts of criminal law that a penal statute should be definite and certain. It should define its orbit with exactitude so that a citizen may be aware of the penalties attendant upon a certain course of conduct. Liberty is a precious attribute of our civilization and a criminal statute is the most extreme example of restraint that our government knows. Fine and imprisonment are harsh deterrents, and the prohibited acts should be defined with care so that only the foolhardy or vicious will be penalized.

As stated in *Vol. 50, American Jurisprudence,* at page 244:

> "In accordance with what is commonly known as the rule of *ejusdem generis* where in a statute general words follow a designation of particular subjects . . ., the meaning of the general words will ordinarily be presumed to be and construed as restricted by the particular designation and as including only things or persons of the same kind, class, character or nature as those specifically enumerated."

In *Kraus vs. United States, 327 U. S. 614*, where the defendant was convicted of violating the Maximum Price Regulation 269, and where the defendant had required buyers to purchase chicken feet or chicken skin at a specified price as a condition of the sale of the poultry and it was charged that this conduct of the defendant was in violation of Section 1429-5 of the regulation, which provides that the regulation "shall not be evaded whether by direct or indirect methods, in connection with any offer, solicitation, agreement, sale, delivery, purchase or receipt of, or relating to, the commodities prices of which are herein regulated, alone or in conjunction with any other commodity, . . ., the Court said:

> "In a very literal sense the liberties and fortunes of others may depend upon his definitions and specifications regarding evasion. Hence to these provisions must be applied the same strict rule of construction that is applied to statutes defining criminal action. In other words, the Administrator's provisions must be explicit and unambiguous in order to sustain a criminal prosecution; they must adequately inform those who are subject to their terms what conduct will be considered evasive so as to bring the criminal penalties of the act into operation. The dividing line between unlawful evasion and lawful action cannot be left to conjecture. The elements of evasive conduct should be so clearly expressed by the Administrator that the ordinary person can know in advance how to avoid an unlawful course of action."

> "In applying this strict rule of construction to the provisions adopted by the Administrator, Courts must take care not to construe so strictly as to defeat the obvious intention of the Administrator. Words used

by him to describe evasive action are to be given their natural and plain meaning . . . But patent omissions and uncertainties cannot be disregarded when dealing with a criminal prosecution. A prosecutor in framing an indictment, a court in interpreting the Administrator's regulations or a jury in judging guilt cannot supply that which the Administrator failed to do by express words or fair implication. Not even the Administrator's interpretations of his own regulations can cure an omission or add certainty and definiteness to otherwise vague language. The prohibited conduct must, for criminal purposes, be set forth with clarity in the regulations . . . Congress has warned the public to look to that source alone to discover what conduct is evasive and hence likely to create criminal liability.

"In the light of these principles we are unable to sustain this conviction of the petitioner . . . ."

In *United States vs. Resnick, 299 U. S. 207,* where the defendant was indicted on charges of selling for fruits and vegetables, two-quart metal hampers which were not of any standard size authorized by the statute and did not come within any tolerance established by the Secretary of Agriculture without having submitted dimension specifications to the Secretary of Agriculture, and where Section 1 of the Act prescribes nine (9) standard sizes and two-quart hampers are not one of them, and Section 4 commands that no manufacturer shall manufacture hampers unless the dimension specifications shall have been submitted to and approved by the Secretary of Agriculture, it was held that the sale of such two-quart hampers were not within the terms of Section 5 of the Act, which

forbade the manufacture and sale of containers that do not comply with the Act. There the Court said:

> "Statutes creating crimes are to be strictly construed in favor of the accused; they may not be held to extend to cases not covered by the words used. Before one may be punished it must appear that his case is plainly within the statute; there are no constructive offenses."

In *United States vs. Weitzel, 246 U. S. 533,* Page 543, it was said:

> "Statutes creating and defining crimes are not to be extended by intendment because the Court thinks the legislature should have made them more comprehensve."

In *United States vs. Harris, 177 U. S. 305,* Page 310, the Court quoted from *United States vs. Wiltberger, 5 Wheat 76,* as follows:

> "The rule that penal laws are to be construed strictly is perhaps not much less old than construction itself. It is founded on the tenderness of the law for the rights of individuals, and on the plain principle that the power of punishment is vested in the legislature and not in the judicial department . . . It would be dangerous indeed to carry the principle that a case which is within the reason or mischief of a statute is within its provisions so far as to punish a crime not enumerated in the statute because it is of equal atrocity or of a kindred character with those which are enumerated."

In *Fasulo vs. United States, 272 U. S. 620,* where the defendant wrote and mailed a letter containing threats

of murder or bodily harm for the purpose of obtaining money and was indicted for violating Section 216 of the Criminal Code and the words of the statute relied on were as follows:

> "Whoever, having devised . . . any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promise, . . . shall, for the purpose of executing such scheme . . . place, or cause to be placed, any letter, . . . in any post office, . . . to be sent or delivered . . . shall be punished."

It was held that the defendant could not be convicted of violating the statute because the use of mails to obtain money by threats of murder is not in furtherance of a scheme to defraud. There the Court said:

> "While for the ascertainment of the true meaning and intention of the words relied on regard is to be had to the evils that called forth the enactment and to the rule that the strict construction of penal statutes does not require the words to be so narrowed as to exclude cases that fairly may be said to be covered by them, it is not permissible for the Court to search for an intention that the words themselves do not suggest . . .
>
> "There are no constructive offenses; and before one can be punished, it must be shown that his case is plainly within the statute.
>
> "We recognize the value of the rule of construing statutes with reference to the evil they were designed to suppress as an important aid in ascertaining the meaning of language in them that is ambiguous and equally susceptible of conflicting constructions. But

this Court has repeatedly held that this rule does not apply to instances that are not embraced in the language employed in the statute, or implied from a fair interpretation of its contents, even though they may involve the same mischief which the statute was designed to suppress."

In *United States vs. Ury, 106 F. 2nd 28,* cited by the government, there was no vagueness in the statute under which the appellee was convicted. The Act plainly said that if anyone removed the marks, required by the Act to be placed on an imported article, he should be convicted. Appellee removed the mark, and in so doing he did what the Act expressly and definitely prohibited. But Sec. 301 (k) does not say that if any person sells at retail in intrastate commerce any food, drug, device or cosmetic which previously had been shipped in bulk in interstate commerce, then such retailer shall be convicted if he does not label such retail sales as provided by the Act.

We earnestly insist that even if Congress had the constitutional power to regulate such isolated retail sales as are here involved, and even if Congress intended to regulate such sales and intended that any retail sale in intrastate commerce of any food, drug or cosmetic that was not labeled as the Act provided would be a crime and punishable by fine and imprisonment, Section 331 (k) of Title 21 of the United States Code is too indefinite as applied to the acts of respondent to be enforceable as a criminal statute. It does not adequately inform respondent that such sales and such labeling in interstate commerce is a crime.

3. If the Federal Food, Drug and Cosmetic Act is properly construed as applying to the acts of respondent, then the Act is unconstitutional and void in that it is in violation of the Tenth Amendment to the Constitution of the United States, and an invasion of the police powers reserved to the several states.

Respondent recognizes that under the commerce clause the Congress has power to regulate intrastate acts when such acts directly and substantially affect interstate commerce, or effectually defeat the particular regulation of interstate commerce in question. So, therefore, the question here is whether the regulation of the labeling of retail sales in intrastate commerce is necessary in order for Congress to prevent the movement in interstate commerce of misbranded foods, drugs, devices or cosmetics.

The commerce clause cannot be construed to reach all intrastate acts which might have an indirect effect upon interstate commerce, for to do so would destroy the distinction between domestic and interstate commerce, which the commerce clause itself has established, and the authority of the State over its domestic concerns would exist only by sufferance of the federal government, and there would be virtually no limit to the federal power and we would have a completely centralized government.

In *Schechter Poultry Corporation vs. United States*, 295 *U. S. 495*, this Court held the sale of sick chickens in intrastate commerce after they had been shipped in interstate commerce, could not have any direct and substantial affect upon such interstate commerce, and that the National Recovery Act, in so far as it sought to regulate

such retail sales, was unconstitutional and void. In the National Recovery Act, as well as in many other Acts, the Congress expressly attempted to regulate transactions affecting commerce, while there is no such language in the Federal Food, Drug and Cosmetic Act.

This case differs from the *United States vs. Darby, 312 U. S. 100,* where it was held the Congress had the power under the commerce clause to prohibit the shipment in interstate commerce of goods produced in violation of the Fair Labor Standards Act. The Darby case is more like *United States vs. Walsh, 331 U. S. 432,* where it was held that Congress had the right under the Federal Food, Drug and Cosmetic Act to punish the giving of a false guaranty by a seller selling misbranded or adulterated drugs to a purchaser regularly engaged in selling such drugs in interstate commerce where it was not shown that the particular misbranded or adulterated drugs had been shipped in interstate commerce by the purchaser.

The case at bar is distinguishable from *Wrightwood Dairy Company vs. United States, 315 U. S. 110,* where it was held that Congress, under the commerce clause, had the power to regulate the intrastate sale of milk in the Chicago Marketing Area, where it was necessary to regulate the price of such intrastate milk in order to make effective its regulation of the price of milk moving interstate into such area.

Also, in the case of *Wickard vs. Filburn, 317 U. S. 111,* it was likewise held that Congress, under the Agricultural Adjustment Act of 1938, in order to regulate the

national supply of wheat, had the right to regulate the production and disposition of Filburn's wheat, even though he was not engaged in interstate commerce.

In both of the Acts construed in the Wrightwood and Filburn cases, there were expressed findings and recitals in the Acts themselves that it was necessary to accomplish the purpose of the legislation to regulate intrastate acts affecting commerce.

In the opinion in the *Wrightwood* case this Court pointed out at page 124 that in the Schechter case "the defendants were not charged with injury to interstate commerce, or interference with persons engaged in that commerce, and that the acts charged had no different relation to or effect upon interstate commerce than like acts in any other local business which handles commodities brought into the State." This quotation respondent submits applies to the case at bar.

In *Federal Trade Commission vs. Bunte Brothers, 312 U. S. 349*, this Court, at page 353, said:

> "Translation of an implication drawn from the special aspects of one statute to a totally different statute is treacherous business. The Interstate Commerce Act and the Federal Trade Commsision Act are widely disparate in their historic setting, in the enterprises which they affect, in the range of control they exercise, and in the relation of these controls to the functioning of the federal system."

There is a wide difference between the regulation of the price and volume of production of agricultural prod-

ucts such as wheat and milk, and the regulation of food and drugs shipped in interstate commerce. If the purpose of the regulation is to regulate the price of interstate milk, there is an actual necessity to regulate the price of intrastate milk which competes with it. If the purpose of the regulation is to control the total supply of wheat in the United States, of necessity the production and disposition of wheat locally grown must be regulated. But it is not necessary for Congress to regulate the retail intrastate sale of food and drugs in order to prohibit the movement in interstate commerce of adulterated and misbranded drugs. Nor would the regulation of the interstate retail sale of food and drugs have any effect upon the efficiency of regulation of the interstate shipment of food and drugs.

In *Cloverleaf Butter Co. vs. Patterson, 315 U. S. 148,* this Court held that the State of Alabama could not seize and condemn unwholesome packing stock butter owned by a manufacturer engaged in renovating butter for sale in interstate commerce, because such State action was inconsistent with the federal regulations under the applicable federal statute. If the Federal Food, Drug and Cosmetic Act is construed as regulating retail intrastate sales, and is held constitutional, then the State regulation of such sales will be rendered invalid and unenforceable under the Cloverleaf decision and the result will be to deny to the several States the power to protect the health of their citizens. Surely the federal power should not be pushed to such an extent. In the opinion in the Cloverleaf case, in discussing the federal act there in question, the Court, at Page 168, said:

"It left the States free to act on the packing stock supplies prior to the time of their delivery to the manufacturer, and to regulate sales of the finished product within their borders."

Since the regulation of intrastate sales of food and drugs is not necessary to the accomplishment of the purpose, and can have no effect upon the prohibiting of the movement in interstate commerce of adulterated food and drugs, Congress has no constitutional power to regulate such intrastate sales, and if it attempted to do so, such regulation is invalid.

CONCLUSION.

We respectfully submit that the judgment of the Court of Appeals should be affirmed because Sec. 301 (k) of the Act is too indefinite to be enforceable as a criminal statute; the Act should be construed as not applying to the intrastate retail sales; and, if construed as applying to such retail sales, it is unconstiutional and void.

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This is to certify that copies of this brief have been served on opposing counsel on this the .... day of November, 1947.

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SUPREME COURT OF THE UNITED STATES.

No. 121.—October Term, 1947.

The United States of America, v. Jordan James Sullivan, Trading as Sullivan's Pharmacy.	On Writ of Certiorari to the United States Circuit Court of Appeals for the Fifth Circuit.

[January 19, 1948.]

Mr. Justice Black delivered the opinion of the Court.

Respondent, a retail druggist in Columbus, Georgia, was charged in two counts of an information with a violation of § 301 (k) of the Federal Food, Drug, and Cosmetics Act of 1938. That section prohibits "the doing of any . . . act with respect to, a . . . drug . . . if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."[1] Section 502 (f) of the Act declares a drug "to be misbranded . . . unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use . . . dangerous to health, or against unsafe dosage . . . as are necessary for the protection of users." The information charged specifically that the respondent had performed certain acts which resulted in sulfathiazole being "misbranded" while "held for sale after shipment in interstate commerce."

[1] "Sec. 301. The following acts and the causing thereof are hereby prohibited:

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded." 52 Stat. 1042, 21 U. S. C. § 331 (k).

The facts alleged were these: A laboratory had shipped in interstate commerce from Chicago, Illinois, to a consignee at Atlanta, Georgia, a number of bottles, each containing 1,000 sulfathiazole tablets. These bottles had labels affixed to them, which, as required by § 502 (f) (1) and (2) of the Act, set out adequate directions for the use of the tablets and adequate warnings to protect ultimate consumers from dangers incident to this use.[2] Respondent bought one of these properly labeled bottles of sulfathiazole tablets from the Atlanta consignee, transferred it to his Columbus, Georgia, drugstore, and there held the tablets for resale. On two separate occasions twelve tablets were removed from the properly labeled and branded bottle, placed in pill boxes, and sold to customers. These boxes were labeled "sulfathiazole." They did not contain the statutorily required adequate directions for use or warnings of danger.

Respondent's motion to dismiss the information was overruled, a jury was waived, evidence was heard, and respondent was convicted under both counts.

The Circuit Court of Appeals reversed. 161 F. 2d 629. The court thought that as a result of respondent's action the sulfathiazole became "misbranded" within the mean-

[2] The following inscription appeared on the bottle labels as a compliance with § 502 (f) (1) which requires directions as to use: "Caution.—To be used only by or on the prescription of a physician." This would appear to constitute adequate directions since it is required by regulation issued by the Administrator pursuant to authority of the Act. 21 C. F. R. Cum. Supp. § 2.106 (b) (3). The following appeared on the label of the bottles as a compliance with § 502 (f) (2) which requires warnings of danger: "Warning.—In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

"Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request."

ing of the Federal Act, and that in its "broadest possible sense" the Act's language "may include what happened." However, it was also of the opinion that the Act ought not to be taken so broadly "but held to apply only to the holding for the first sale by the importer after interstate shipment." Thus the Circuit Court of Appeals interpreted the statutory language of § 301 (k) "while such article is held for sale after shipment in interstate commerce" as though Congress had said "while such article is held for sale by a person who had himself received it by way of a shipment in interstate commerce." We granted certiorari to review this important question concerning the Act's coverage.

First. The narrow construction given § 301 (k) rested not so much upon its language as upon the Circuit Court's view of the consequences that might result from the broader interpretation urged by the Government. The court pointed out that the retail sales here involved were made in Columbus nine months after this sulfathiazole had been shipped from Chicago to Atlanta. It was impressed by the fact that, if the statutory language "while such article is held for sale after shipment in interstate commerce" should be given its literal meaning, the criminal provisions relied on would "apply to all intrastate sales of imported drugs after any number of intermediate sales within the State and after any lapse of time; and not only to such sales of drugs, but also to similar retail sales of food, devices and cosmetics, for all these are equally covered by these provisions of the Act." The court emphasized that such consequences would result in far-reaching inroads upon customary control by local authorities of traditionally local activities, and that a purpose to afford local retail purchasers federal protection from harmful foods, drugs and cosmetics should not be ascribed to Congress in the absence of an exceptionally clear mandate, citing *Federal Trade Commission* v. *Bunte*

Bros., 312 U. S. 349. Another reason of the court for refraining from construing the Act as applicable to articles misbranded while held for retail sale, even though the articles had previously been shipped in interstate commerce, was its opinion that such a construction would raise grave doubts as to the Act's constitutionality. In support of this position the court cited *Labor Board* v. *Jones & Laughlin Steel Corp.*, 301 U. S. 1, 30, and *Schechter Poultry Corp.* v. *United States*, 295 U. S. 495.

A restrictive interpretation should not be given a statute merely because Congress has chosen to depart from custom or because giving effect to the express language employed by Congress might require a court to face a constitutional question. And none of the foregoing cases, nor any other on which they relied, authorizes a court in interpreting a statute to depart from its clear meaning. When it is reasonably plain that Congress meant its Act to prohibit certain conduct, no one of the above references justifies a distortion of the congressional purpose, not even if the clearly correct purpose makes marked deviations from custom or leads inevitably to a holding of constitutional invalidity. Although criminal statutes must be so precise and unambiguous that the ordinary person can know how to avoid unlawful conduct, see *Kraus & Bros., Inc.* v. *United States*, 327 U. S. 614, 621–622, even in determining whether such statutes meet that test, they should be given their fair meaning in accord with the evident intent of Congress. *United States* v. *Raynor*, 302 U. S. 540, 552.

Second. Another consideration that moved the Circuit Court of Appeals to give the statute a narrow construction was its belief that the holding in this case with reference to misbranding of drugs by a retail druggist would necessarily apply also to "similar retail sales of food, devices and cosmetics, for all of these," the court said, "are equally covered by the same provisions of the Act." And in this

Court the effect of such a possible coverage of the Act is graphically magnified. We are told that its application to these local sales of sulfathiazole would logically require all retail grocers and beauty parlor operators to reproduce the bulk container labels on each individual item when it is taken from the container to sell to a purchaser. It is even prophesied that, if § 301 (k) is given the interpretation urged by the Government, it will later be applied so as to require retail merchants to label sticks of candy and sardines when removed from their containers for sale.

The scope of the offense which Congress defined is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications of its different misbranding provisions which relate to food, cosmetics, and the like. There will be opportunity enough to consider such contingencies should they ever arise. It may now be noted, however, that the Administrator of the Act is given rather broad discretion—broad enough undoubtedly to enable him to perform his duties fairly without wasting his efforts on what may be no more than technical infractions of law. As an illustration of the Administrator's discretion, § 306 permits him to excuse minor violations with a warning if he believes that the public interest will thereby be adequately served. And the Administrator is given extensive authority under §§ 405, 503 and 603 to issue regulations exempting from the labeling requirements many articles that otherwise would fall within this portion of the Act. The provisions of § 405 with regard to food apparently are broad enough to permit the relaxation of some of the labeling requirements which might otherwise impose a burden on retailers out of proportion to their value to the consumer.

Third. When we seek the meaning of § 301 (k) from its language we find that the offense it creates and which is here charged requires the doing of some act with respect

to a drug (1) which results in its being misbranded, (2) while the article is held for sale "after shipment in interstate commerce." Respondent has not seriously contended that the "misbranded" portion of § 301 (k) is ambiguous. Section 502 (f), as has been seen, provides that a drug is misbranded unless the labeling contains adequate directions and adequate warnings. The labeling here did not contain the information which § 502 (f) requires. There is a suggestion here that, although alteration, mutilation, destruction, or obliteration of the bottle label would have been a "misbranding," transferring the pills to non-branded boxes would not have been, so long as the labeling on the empty bottle was not disturbed. Such an argument cannot be sustained. For the chief purpose of forbidding the destruction of the label is to keep it intact for the information and protection of the consumer. That purpose would be frustrated when the pills the consumer buys are not labeled as required, whether the label has been torn from the original container or the pills have been transferred from it to a non-labeled one. We find no ambiguity in the misbranding language of the Act.

Furthermore, it would require great ingenuity to discover ambiguity in the additional requirement of § 301 (k) that the misbranding occur "while such article is held for sale after shipment in interstate commerce." The words accurately describe respondent's conduct here. He held the drugs for sale after they had been shipped in interstate commerce from Chicago to Atlanta. It is true that respondent bought them nine months after the interstate shipment had been completed by their delivery to another consignee. But the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had

received the articles at the end of the interstate shipment. Accordingly we find that the conduct of the respondent falls within the literal language of § 301 (k).

Fourth. Given the meaning that we have found the literal language of § 301 (k) to have, it is thoroughly consistent with the general aims and purposes of the Act. For the Act as a whole was designed primarily to protect consumers from dangerous products. This Court so recognized in *United States* v. *Dotterweich*, 320 U. S. 277, 282, after reviewing the House and Senate Committee Reports on the bill that became law. Its purpose was to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer. Section 301 (a) forbids the "introduction or delivery for introduction into interstate commerce" of misbranded or adulterated drugs; § 301 (b) forbids the misbranding or adulteration of drugs while "in interstate commerce"; and § 301 (c) prohibits the "receipt in interstate commerce" of any misbranded or adulterated drug, and "the delivery or proferred delivery thereof for pay or otherwise." But these three paragraphs alone would not supply protection all the way to the consumer. The words of paragraph (k) "while such article is held for sale after shipment in interstate commerce" apparently were designed to fill this gap and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer. Doubtless it was this purpose to insure federal protection until the very moment the articles passed into the hands of the consumer by way of an intrastate transaction that moved the House Committee on Interstate and Foreign Commerce to report on this section of the Act as follows: "In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k)

has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment."[3] We hold that § 301 (k) prohibits the misbranding charged in the information.

Fifth. It is contended that the Act as we have construed it is beyond any authority granted Congress by the Constitution and that it invades the ~~power of~~ the States. A similar challenge was made against the Pure Food and Drug Act of 1906, 34 Stat. 768, and rejected, in *McDermott* v. *Wisconsin*, 228 U. S. 115. That Act did not contain § 301 (k), but it did prohibit misbranding and authorized seizure of misbranded articles after they were shipped from one State to another, so long as they remained "unsold." The authority of Congress to make this requirement was upheld as a proper exercise of its powers under the commerce clause. There are two variants between the circumstances of that case and this one. In the *McDermott* case the labels involved were on the original containers; here the labels are required to be put on other than the original containers—the boxes to which the tablets were transferred. Also, in the *McDermott* case the possessor of the labeled cans held for sale had himself received them by way of an interstate sale and shipment; here, while the petitioner had received the sulfathiazole by way of an intrastate sale and shipment, he bought it from a wholesaler who had received it as the direct consignee of an interstate shipment. These variants are not sufficient we think to detract from the applicability of the *McDermott* holding to the present decision. In both cases alike the question relates to the constitutional power of Congress under the commerce clause to regulate the branding of articles that have completed an interstate shipment and are being held for future sales in purely local or intrastate commerce.

[3] H. Rep. 2139, 75th Cong., 3d Sess., 3.

The reasons given for the *McDermott* holding therefore are equally applicable and persuasive here. And many cases decided since the *McDermott* decision lend support to the validity of § 301 (k). See, *e. g.*, *United States* v. *Walsh*, 331 U. S. 432; *Wickard* v. *Filburn*, 317 U. S. 111; *United States* v. *Wrightwood Dairy Co.*, 315 U. S. 110; *United States* v. *Darby*, 312 U. S. 100; see *United States* v. *Olsen*, 161 F. 2d 669.

Reversed.

SUPREME COURT OF THE UNITED STATES

No. 121.—October Term, 1947.

The United States of America, v. Jordan James Sullivan, Trading as Sullivan's Pharmacy.	On Writ of Certiorari to the United States Circuit Court of Appeals for the Fifth Circuit.

[January 19, 1948.]

Mr. Justice Rutledge, concurring.

This case has been presented as if the Federal Food, Drug, and Cosmetics Act of 1938 had posed an inescapable dilemma. It is said that we must either (1) ignore Congress' obvious intention to protect ultimate consumers of drugs through labeling requirements literally and plainly made applicable to the sales in this case or (2) make criminal every corner grocer who takes a stick of candy from a properly labeled container and sells it to a child without wrapping it in a similar label.

The trouble-making factor is not found in the statute's provisions relating specifically to drugs. Those provisions taken by themselves are clear and unequivocal in the expressed purpose to protect the ultimate consumer by the labeling requirements. So is the legislative history. Standing alone, therefore, the drug provisions would cover this case without room for serious question.

However, those provisions do not stand entirely separate and independent in the Act's structure. In some respects, particularly in § 301 (k), they are interlaced with provisions affecting food and cosmetics. And from this fact is drawn the conclusion that this decision necessarily will control future decisions concerning those very different commodities.

If the statute as written required this, furnishing no substantial basis for differentiating such cases, the deci-

sion here would be more difficult than I conceive it to be. But I do not think the statute has laid the trap with which we are said to be faced. Only an oversimplified view of its terms and effects could produce that result.

The Act is long and complicated. Its numerous provisions treat the very different subjects of drugs, food and cosmetics alike in some respects, differently in others. The differences are as important as the similarities, and cannot be ignored. More is necessary for construction of the statute than looking merely to the terms of §§ 301 (k) and 502 (f).

It is true that § 301 (k) deals indiscriminately with food, drugs, devices and cosmetics, on the surface of its terms alone. Hence it is said that the transfer of sulfathiazole, a highly dangerous drug, from a bulk container to a small box for retail sale, could not be "any other act" unless a similar transfer of candies, usually harmless, also would be "any other act." From this hypothesis it is then concluded that the phrase must be interpreted with reference to the particularities which precede it, namely, "alteration, mutilation, destruction, obliteration or removal" of any part of the label, and must be limited by those particularities.

That construction almost, if not quite, removes "any other act" from the section. And by doing so it goes far to emasculate the section's effective enforcement, especially in relation to drugs. Any dealer holding drugs for sale after shipment in interstate commerce could avoid the statute's effect simply by leaving the label intact, removing the contents from the bulk container, and selling them, however deadly, in broken parcels without label or warning.

I do not think Congress meant the phrase to be so disastrously limited. For the "doing of any other act

with respect to a food, drug, device, or cosmetic" is prohibited by § 301 (k) only "if such act . . . results in such article being misbranded." And the statute provides, not a single common definition of misbranding for foods, drugs and cosmetics, but separate and differing sections on misbranded foods, misbranded drugs and devices, and misbranded cosmetics. §§ 403, 502, 602.

The term "misbranded" as used in § 301 (k) therefore is not one of uniform connotation. On the contrary, its meaning is variable in relation to the different commodities and the sections defining their misbranding. So also necessarily is the meaning of "any other act," which produces those misbranding consequences. Each of the three sections therefore must be taken into account in determining the meaning and intended scope of application for § 301 (k) in relation to the specific type of commodity involved in the particular sale, if Congress' will is not to be overridden by broadside generalization glossed upon the statute. As might have been expected, Congress did not lump food, drugs and cosmetics in one indiscriminate hopper for the purpose of applying § 301 (k), either in respect to misbranding or as to "any other act" which produces that consequence. Brief reference to the several misbranding sections incorporated by reference in § 301 (k) substantiates this conclusion.

The three sections contain some common provisions.[1] But the fact that each section is also different from the other two in important respects indicates that each broad subdivision of the Act presents different problems of interpretation. Neither the misbranded foods section nor the misbranded cosmetics section contains any provision directly comparable to § 502 (f), which the respondent here has violated. That section, however, is to be con-

[1] *E. g.*, §§ 403 (a), 502 (a) and 602 (a) are in identical language.

trasted with § 403 (k), one of the subsections dealing with misbranded foods. Comparison of the two provisions indicates that the doing of a particular act with respect to a drug may result in misbranding, whereas the same method of selling food would be proper.

Section 502 (f) provides that a drug shall be deemed to be misbranded:

> "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement."[2]

This provision, dealing with directions for use and warnings against improper use, in terms is designed "for the protection of users." To be effective, this protection requires regulation of the label which the container bears when the drug reaches the ultimate consumer.[3] The legislative history leaves no doubt that the draftsmen and sponsors realized the importance of having dangerous drugs properly labeled at the time of use, not just at the time of sale.[4] The intent to protect the public health is further emphasized by the limited scope of the proviso, which directs the Administrator to make exemptions only when compliance with clause (1) "is not necessary for the protection of the public health."

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[2] See S. Rep. No. 361, 74th Cong., 1st Sess. 19.

[3] See H. R. Rep. No. 2139, 75th Cong., 3d Sess. 8.

Section 403 (k), which contains the principal basis for "making every retail grocer a criminal," is very different. By its terms food is deemed to be misbranded:

> "If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream."

The section, in contrast to § 502 (f)'s comprehensive coverage of drugs, applies not to all foods shipped interstate, but only to the restricted classes containing artificial flavoring, or coloring, or chemical preservatives. The labeling requirement is much simpler. And the proviso confers a much broader power of exemption upon the Administrator than does the proviso of § 502 (f). Under the latter he is given no power to exempt on the ground that compliance is impracticable. He cannot weigh business convenience against protection of the public health. Only where he finds that labeling is not necessary to that protection is he authorized to create an exemption for drugs and devices. Health security is not only the first, it is the exclusive, criterion.

Under § 403 (k), however, in dealing with foods the Administrator can dispense with labels much more broadly. In terms the criterion for his action becomes "the extent that compliance . . . is impracticable" rather than, as under § 502 (f), "where any requirement of clause (1) [adequate directions for use] . . . is not necessary for the protection of the public health." Practical considerations affecting the burden of compliance by man-

ufacturers and retailers, irrelevant under § 502 (f), become controlling under § 403 (k). Thus under the statute's intent a much more rigid and invariable compliance with the labeling requirements for drugs is contemplated than for those with foods, apart from its greatly narrower coverage of the latter. And the difficulty of compliance with those requirements for such articles as candies explains the difference in the two provisos.[4]

These differences, and particularly the differences in the provisos, have a direct and an intended relation to the problem of enforcement. The labeling requirements for foods are given much narrower and more selective scope for application than those for drugs, a difference magnified by the conversely differing room allowed for exemptions. What is perhaps equally important, the provisos are relevant to enforcement beyond specific action taken by the Administrator to create exemptions.

His duty under both sections is cast in mandatory terms. Whether or not he can be forced by mandamus to act in certain situations, his failure to act in some would seem to be clearly in violation of his duty. Obviously there must be many more instances where compliance with the labeling requirements for foods will be "impracticable" than where compliance with the very different requirements

[4] "The proviso of this paragraph likewise requires the establishment of regulations exempting packages of assorted foods from the naming of ingredients or from their appearance in the order of predominance by weight where, under good manufacturing practice, label declaration of such information is impracticable. This provision will be particularly applicable, for example, to assorted confections, which under normal manufacturing practices may vary from package to package not only with respect to identity of ingredients but also in regard to the relative proportions of such ingredients as are common to all packages." S. Rep. No. 493, 73d Cong., 2d Sess. 12. The proviso discussed is in § 403 (i), not in § 403 (k); but the discussion brings out the sort of considerations which require exemption when compliance is impracticable.

for drugs will not be "necessary for the protection of the public health." That difference is obviously important for enforcement, particularly by criminal prosecution. I think it is one which courts are entitled to take into account when called upon to punish violations. The authors of the legislation recognized expressly that "technical, innocent violations . . . will frequently arise." S. Rep. No. 152, 75th Cong., 1st Sess. 4. In other words, there will be conduct which may be prohibited by the Act's literal wording, but which nevertheless should be immune to prosecution.

When that situation arises, as it often may with reference to foods, by virtue of the Administrator's failure to discharge his duty to create exemptions before the dealer's questioned action takes place, that failure in my judgment is a matter for the court's consideration in determining whether prosecution should proceed. Whenever it is made to appear that the violation is a "technical, innocent" one, an act for which the Administrator should have made exemption as required by § 403 (k), the prosecution should be stopped. This Court has not hesitated to direct retroactive administrative determination of private rights when that unusual course seemed to it the appropriate solution for their determination. *Addison* v. *Holly Hill Fruit Products*, 322 U. S. 607. If that is permissible in civil litigation, there is much greater reason for the analogous step of taking into account in a criminal prosecution an administrative officer's failure to act when the commanded action, if taken, would have made prosecution impossible.

It is clear therefore that the corner grocer occupies no such position of jeopardy under this legislation as the druggist, and that the meaning of § 301 (k) is not identical for the two, either as to what amounts to misbranding or as to what is "the doing of any . . . act" creating that result. The supposed dilemma is false.

Congress had power to impose the drug restrictions, they are clearly applicable to this case, the decision does not rule the corner grocer selling candy, and the judgment should be reversed. I therefore join in the Court's judgment and opinion to that effect.

SUPREME COURT OF THE UNITED STATES

No. 121.—October Term, 1947.

The United States of America, *v.* Jordan James Sullivan, Trading as Sullivan's Pharmacy.	On Writ of Certiorari to the United States Circuit Court of Appeals for the Fifth Circuit.

[January 19, 1948.]

Mr. Justice Frankfurter, dissenting.

If it takes nine pages to determine the scope of a statute, its meaning can hardly be so clear that he who runs may read, or that even he who reads may read. Generalities regarding the effect to be given to the "clear meaning" of a statute do not make the meaning of a particular statute "clear." The Court's opinion barely faces what, on the balance of considerations, seems to me to be the controlling difficulty in its rendering of § 301 (k) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 1042; 21 U. S. C. § 331 (k). That section no doubt relates to articles "held for sale after shipment in interstate commerce and results in such article being misbranded." But an article is "misbranded" only if there is "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic." Here there was no "alteration, mutilation, destruction, oblieration, or removal" of any part of the label. The decisive question is whether taking a unit from a container and putting it in a bag, whether it be food, drug or cosmetic, is doing "any other act" in the context in which that phrase is used in the

setting of the Federal Food, Drug, and Cosmetic Act and particularly of § 301 (k).[1]

As bearing upon the appropriate answer to this question, it cannot be that a transfer from a jar, the bulk container, to a small paper bag, without transferring the label of the jar to the paper bag, is "any other act" when applied to a drug, but not "any other act" when applied to candies or cosmetics. Before we reach the possible discretion that may be exercised in prosecuting a certain conduct, it must be determined whether there is anything to prosecute. Therefore, it cannot be put off to some other day to determine whether "any other act" in § 301 (k) applies to the ordinary retail sale of candies or cosmetics in every drug store or grocery throughout the land, and so places every corner grocery and drug store under the hazard that the Administrator may report such conduct for prosecution. That question is now here. It is part of this very case, for the simple reason that the prohibited conduct of § 301 (k) applies with equal force, through the same phrase, to food, drugs and cosmetics insofar as they are required to be labeled. See §§ 403, 502, and 602 of the Act.

It is this inescapable conjunction of food, drugs and cosmetics in the prohibition of § 301 (k) that calls for a consideration of the phrase "or the doing of any other act," in the context of the rest of the sentence and with due regard for the important fact that the States are also deeply concerned with the protection of the health and welfare of their citizens on transactions peculiarly within local enforcing powers. So considered, "the doing of any other act" should be read with the meaning which radiates

[1] "The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded."

to that loose phrase from the particularities that precede it, namely "alteration, mutilation, destruction, obliteration, or removal" of any part of the label. To disregard all these considerations and then find "a clear meaning" is to reach a sum by omitting figures to be added. There is nothing in the legislative history of the Act, including the excerpt from the Committee Report on which reliance is placed, to give the slightest basis for inferring that Congress contemplated what the Court now finds in the statute. The statute in its entirety was of course intended to protect the ultimate consumer. This is no more true in regard to the requirements pertaining to drugs than of those pertaining to food. As to the reach of the statute—the means by which its ultimate purpose is to be achieved—the legislative history sheds precisely the same light on the provisions pertaining to food as on the provisions pertaining to drugs. If differentiations are to be made in the enforcement of the Act and in the meaning which the ordinary person is to derive from the Act, such differentiations are interpolations of construction. They are not expressions by Congress.

In the light of this approach to the problem of construction presented by this Act, I would affirm the judgment below.

MR. JUSTICE REED and MR. JUSTICE JACKSON join in this dissent.